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LIFTING THE BARRIERS EXCLUDING PEOPLE LIVING WITH DISABILITIES FROM THE BENEFITS OF INCLUSION IN RESEARCH STUDIES

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As the COVID-19 virus continues to rage out of control in the United States, there are thousands of ongoing clinical trials seeking to develop even a single effective treatment or vaccine. But the only access to the products being tested is by enrolling in a Food and Drug Administration (FDA) supervised clinical trial. And inclusion in a clinical trial has always been by invitation only. This paper addresses a long-ignored injustice: on the thirtieth anniversary of the Americans with Disabilities Act (“ADA”) people living with disabilities have found that they are rarely on the clinical trial invitation list. This paper will be the first law review article to focus on the widespread exclusion of people living with disabilities from research studies. Although the situation has attracted some notice in bioethics, public health, and disability advocacy communities, there has never been an effort to identify the entities that fund and conduct research as covered entities subject to the ADA. This paper will make the case for immediate action by the Justice Department to ensure that all covered entities are aware of their obligations under the ADA both to remove the barriers that are either directly or by effect excluding people living with disabilities and to take proactive steps to promote their inclusion.

It will do so by first marshalling the evidence of exclusion and its resulting harm and then analyzing the characteristics of entities conducting research studies that make them covered entities under the ADA. Moreover, the Article addresses directly the most likely justifications for excluding people living with disabilities, which are of the same type routinely rejected by courts. Adoption of universal design principles in research studies, such as adding captions to materials necessary for communicating with potential participants, is only one of many steps that could be implemented immediately.

INTRODUCTION.....	492
I. EXCLUSION OF PEOPLE WITH DISABILITIES FROM RESEARCH: THE SCOPE OF THE PROBLEM	498
A. Who Are People Living With Disabilities?	498
B. What Makes People With Disabilities A Disparately Impacted Population In Terms Of Health Care Results?	499
C. Documenting Exclusion from Research.....	501
D. The Role of Precision Medicine in Encouraging Diverse Participation in Research	504
E. Recognition of Exclusion by Private Funders.....	507
F. Finding Evidence of Harm from Exclusion from the Experience of Other Excluded Populations	508
II. HARM CAUSED BY EXCLUSION FROM RESEARCH	510
A. Population-Based Harm Caused to People with Disabilities by Exclusion from Research.....	510

1. Harm from lack of information about conditions that affect the general population but may impact people living with disabilities differently	510
2. Harm from lack of knowledge specific to the disabling condition	511
3. Dignitary harm	512
B. <i>Harm of Exclusion from Research That Provides Individual Participants a Direct Benefit: The Case of Clinical Trials</i>	512
C. <i>Harm to Society from Excluding People with Disabilities</i>	514
III. LOOKING FOR THE CAUSES OF EXCLUSION	514
A. <i>Exclusion at the Starting Gate: Study Designs that Limit Subject Selection</i>	515
B. <i>Exclusion as Protection: Historical Abuse of People with Mental Illness and Developmental Disabilities in the Name Research</i>	516
C. <i>Addressing Perceptions That People Living with Disabilities Are Not Interested in Research</i>	522
D. <i>Lack of Researchers Who Themselves Live with Disabilities</i>	523
E. <i>Exclusion Because of Study Design</i>	524
F. <i>Reasons for Exclusion of People with Disabilities from Exclusion of Other Populations</i>	526
G. <i>Justifications for Exclusion</i>	528
1. Adding cost to the study	528
2. Affecting validity of results	528
IV. DEVELOPING A LEGAL RESPONSE TO EXCLUSION: THE AMERICANS WITH DISABILITIES ACT	529
A. <i>An Overview of Applying Legal Analysis to Disability-Based Discrimination in Research Studies</i>	530
B. <i>Legal Protection Against Disability-Based Discrimination</i>	531
C. <i>Making a Prima Facie Case for Discrimination Under the ADA</i>	535
D. <i>Proving Discrimination</i>	536
1. Disparate treatment: deliberate discrimination	538
2. Justifying inaccessible research	539
E. <i>How do Research Sites or Sponsors Qualify as "Covered Entities"?</i>	540
1. Research conducted by the federal government: a vaccine trial at NIH	540
2. Research funded by the federal government	541
3. Exclusion from a clinical trial not directly funded by the federal government	542
4. Research conducted by or at a private entity which receives federal funding: the case of Dolly Parton	544
5. Exclusion from biomedical research in a place that does not receive federal funding but does provide health care to the public	545

F. <i>Obligations to Eliminate Barriers to Access under Title III of the ADA</i>	546
1. Biomedical research studies conducted by private entities who do not provide healthcare	546
2. Making reasonable accommodations under Title III of the ADA ..	549
3. Obligation of entities subject to Title III to eliminate barriers to access to a research study	549
4. Provision of auxiliary aids and services	551
5. Is exclusion of people with disabilities a necessary action which would otherwise fundamentally alter the character of the research? ..	552
G. <i>Exclusion from Research Conducted by Entities Which Provide Health Care to the Public</i>	555
H. <i>Is Exclusion from a Clinical Trial Exclusion from Healthcare?</i>	556
I. <i>Is This a Claim that People Living with Disabilities Have a Right to Participate in Research Studies?</i>	557
CONCLUSIONS	558

INTRODUCTION

As this article is being written, the world faces a global pandemic caused by the rapid spread of a new virus¹ to which no one is yet immune, from which millions have become infected² and hundreds of thousands have already died,³ and for which—during the first year of the pandemic—there were no known effective vaccines⁴ or treatments.⁵ There is already evidence that people living with disabilities⁶ are not just being disparately impacted by

¹ *COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-nCoV/index.html> [<https://perma.cc/X5Z7-VM7E>] (last visited Feb. 1, 2021).

² *CDC COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html> [<https://perma.cc/A7TM-P6SG>] (last visited Jan. 25, 2021).

³ To view a more accurate death count attributable to COVID-19 at any point in time, see *Excess Deaths Associated with COVID-19*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm [<https://perma.cc/88CX-66FG>] (last visited Jan. 25, 2021); *Daily Updates of Totals by Week and State*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm> [<https://perma.cc/N8Z6-RPZT>] (last visited Feb. 1, 2021).

⁴ *Coronavirus Disease (COVID-19) Advice for the Public: Mythbusters*, WORLD HEALTH ORG., <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters> [<https://perma.cc/BSB3-DYSA>] (last visited Jan. 25, 2021).

⁵ See *id.* (“There is currently no licensed medication to cure COVID-19.”).

⁶ Language matters. This article will use the words “people living with disabilities” to describe the human beings who are discriminated against by being excluded from research, but will reproduce as written descriptions that are part of existing statutes, cases, and other

the virus but are being excluded from ICU care.⁷ The only options for people who seek to avoid infection are to stay at home or take basic public health hygiene precautions. As the Mayo Clinic describes the situation, “[w]ith the number of COVID-19 cases and deaths rising with each day, there is perhaps no more pressing need in medicine than to identify safe and effective therapies to prevent SARS-CoV-2 infections and to lessen the severity of the resulting COVID-19 respiratory illness.”⁸ As one commenter recently noted, “[e]xperimental treatments are standard of care in the absence of an approved treatment.”⁹

documents. It does so based on guidelines issued by The National Center on Disability and Journalism at Arizona State University, which advocates “people-first language unless otherwise indicated by the source.” *Disability Language Style Guide*, NAT’L CTR. ON DISABILITY AND JOURNALISM, <https://ncdj.org/style-guide> [<https://perma.cc/RV4D-9LLB>] (last visited Feb. 16, 2021). See Labib Rahman, *Disability Language Guide*, STANFORD DISABILITY INITIATIVE BOARD (July 2019), https://disability.stanford.edu/sites/g/files/sbiybj1401/f/disability-language-guide-stanford_1.pdf [<https://perma.cc/6ALY-7E3J>] (stating that “there is not a monolithic language style preference shared across all the people who have a disability”).

⁷ Since the pandemic is still ongoing, it is too early to know the scope of actual exclusions although there have been reports of individual incidents. See Joseph Shapiro, *Oregon Hospitals Didn’t Have Shortages. So Why Were Disabled People Denied Care?*, NPR (Dec. 21, 2020, 3:21 PM), <https://www.npr.org/2020/12/21/946292119/oregon-hospitals-didnt-have-shortages-so-why-were-disabled-people-denied-care> [<https://perma.cc/95PK-JVFW>] (describing an incident in Oregon where a disability rights organization intervened on behalf of an individual with intellectual disability who came to the hospital with COVID-19 and was not given access to a ventilator despite difficulty with breathing. The patient was transferred to another hospital where she was put on a ventilator and recovered. An investigation found that the patient was “being inappropriately influenced about life-sustaining treatment. And the physician in that case talked about the quote ‘low quality of life’ of a person with a disability.”). For an interim overview of some of the concerns expressed about the impact of the pandemic on people living with disabilities, see Elizabeth Pendo, *COVID-19 and Disability-Based Discrimination in Health Care*, A.B.A. (May 22, 2020), <https://www.americanbar.org/groups/diversity/disabilityrights/resources/covid19-disability-discrimination/> [<https://perma.cc/XHF8-C3XE>] (“Governmental and private responses to the COVID-19 pandemic can compound these longstanding health inequalities. In particular, because the COVID-19 pandemic places tremendous strain on our health care system, states, health care facilities, and professional organizations are developing triage protocols to determine how to allocate critical health care resources, especially ventilators, when there is not enough capacity to treat all patients. Disability advocates and organizations have raised serious concerns about the impact of triage policies that exclude, disadvantage, or otherwise discriminate on the basis of disability.”).

⁸ *Mayo Clinic Researchers Double Down on COVID-19*, MAYO CLINIC, <https://www.mayo.edu/research/covid-19-research> [<https://perma.cc/94VH-HL79>] (last visited Jan. 23, 2021).

⁹ Glenn Ellis, *COVID-19 Vaccine and Treatment Research*, PHILA. TRIB. (July 14, 2020), https://www.phillytrib.com/news/glenn-ellis-covid-19-vaccine-and-treatment-research/article_0a81d801-165c-503d-8d77-c5aa2f5c4ec0.html [<https://perma.cc/53VU-VSGX>].

There is nothing new about people living with disabilities being even more underserved during times of emergency.¹⁰ Professor Sharona Hoffman, citing the experiences of people with psychiatric disabilities after severe hurricanes as reported by the National Council on Disability, warned in 2009 “that during triaging processes, some health care providers may determine that individuals with disabilities are of a lower priority than others because treating them is more difficult or complicated.”¹¹ Health care crises also intersect with the life experiences of people living with disabilities that can contribute to bad health outcomes. As Professor Jasmine Harris explains, as a result of “the persistence of social stigma[,]” “[p]eople with disabilities continue to be un- and underemployed and under-educated on the basis of false conceptions of their agency and humanity.”¹² Therefore, as a population, people living with disabilities have less disposable income than the general population of the United States and are less able to bear the costs of travel to research sites.¹³

If this were not enough, the situation today involving a new deadly virus with no available effective treatment is eerily reminiscent of the situation which led to the creation of a grassroots movement to gain access

¹⁰ See *COVID-19 Poses Unique Challenges for People with Disabilities*, HUB (Apr. 23, 2020), <https://hub.jhu.edu/2020/04/23/how-covid-19-affects-people-with-disabilities/> [<https://perma.cc/J9WK-ZFUD>] (describing how difficult the pandemic has been for people with disabilities who may depend on the assistance of others to comply with social distancing rules, for people with communication deficits to get the information they need when everyone is wearing personal protective equipment, and for people who rely on state mobility services to take advantage of drive-up testing sites).

¹¹ Sharona Hoffman, *Preparing for Disaster: Protecting the Most Vulnerable in Emergencies*, 42 U.C. DAVIS L. REV. 1491, 1500 (2009) (citing NAT’L COUNCIL ON DISABILITY, THE NEEDS OF PEOPLE WITH PSYCHIATRIC DISABILITIES DURING AND AFTER HURRICANES KATRINA AND RITA: POSITION PAPER AND RECOMMENDATIONS 6 (2006), <https://ncd.gov/publications/2006/07142006> [<https://perma.cc/477C-N8YQ>]).

¹² Jasmine E. Harris, *Processing Disability*, 64 AM. U. L. REV. 457, 461 (2015); see also *Disability & Socioeconomic Status*, AM. PSYCH. ASS’N, <https://www.apa.org/pi/ses/resources/publications/disability> [<https://perma.cc/E9ST-QHPT>] (last visited Jan. 21, 2021) (“Results from the American Community Survey . . . reveal significant disparities in the median incomes for those with and without disabilities. Median earnings for people with no disability were over \$30,469, compared to the \$20,250 median income reported for individuals with a disability.”) (citation omitted); Anthony Hicks, *Disabled Americans More Likely to Be Poor and Ignored*, COM. APPEAL (Jan. 4, 2018, 5:20 PM), <https://www.commercialappeal.com/story/opinion/contributors/2018/01/04/disabled-americans-more-likely-poor-and-ignored/1002839001/> [<https://perma.cc/A9UT-QR8A>] (describing the broad occurrence of poverty among people with disabilities).

¹³ Cost of travel is a barrier to many underserved populations. See generally Deborah Watkins Bruner, Stephanie L. Pugh, Katherine A. Yeager, Jesse Bruner & Walter Curran Jr., *Cartographic Mapping and Travel Burden to Assess and Develop Strategies to Improve Minority Access to National Cancer Clinical Trials*, 93 INT’L J. RADIATION ONCOLOGY BIOLOGY PHYSICS 702, 708 (2015) (noting that participation in clinical trials can be improved by focusing on subjects who have difficult difficulty traveling to drug trial sites).

to clinical trials during the early days of the AIDS epidemic,¹⁴ particularly in light of Dr. Anthony Fauci's leading role in overseeing drug development in both outbreaks.¹⁵

Because there are no approved treatments, people who contract the virus must depend on the availability of high intensity hospital care and access to one of many, by definition, experimental treatments through either enrolling in a clinical drug trial¹⁶ or seeking early access to a drug still under review.¹⁷ No curative drug has yet been proved safe and effective.¹⁸ And we

¹⁴ These similarities will be discussed in more detail *infra* in Section II.B. To learn more about this grassroots movement, ACT UP, see MATT BRIM, CUNY ACAD. WORKS, STUDY GUIDE FOR UNITED IN ANGER: A HISTORY OF ACT UP (2012), http://academicworks.cuny.edu/cgi/viewcontent.cgi?article=1001&context=si_oers [<https://perma.cc/MS84-627C>]. It is also important to note that ACT UP's concern was as much about the FDA's slowness in encouraging clinical trials of prospective treatments as it was about exclusions from existing trials.

¹⁵ See Dave Davies, *Long Before COVID-19, Dr. Anthony Fauci 'Changed Medicine in America Forever'*, NPR (Apr. 16, 2020 1:12 PM), <https://www.npr.org/sections/health-shots/2020/04/16/834873162/long-before-covid-19-dr-tony-fauci-changed-medicine-in-america-forever> [<https://perma.cc/VEN6-EXDB>] (“[D]uring the height of the AIDS epidemic, Fauci worked with activists to amend the way the government handles clinical drug trials,” which “increased the number of patients who had access to experimental HIV/AIDS treatments[.] . . . saved countless lives,” and, as Michael Specter puts it, “basically forced people to realize that you can't run drug trials and decide what to do with patients without ever consulting patients,” which “changed medicine in America forever.”).

¹⁶ This article will use the phrase “clinical drug trial” to mean any study with human participants conducted with the purpose of getting information about a drug or device. This is somewhat broader than the way the phrase is used by the Food and Drug Administration, which limits this phrase to studies conducted by private entities for the purpose of gathering information to apply for permission to sell the drug or vaccine in the United States. However, the crisis of the COVID-19 pandemic has blurred the already fuzzy lines between public and private sponsors of drug trials to the extent that using a variety of words for the concept of a person in need of medical care seeking access to a drug or device not yet on the market would be more confusing than helpful. For an overview of how the FDA normally regulates clinical drug trials of the type being conducted for potential COVID-19 cures, see Joshua D. Wallach, Joseph S. Ross & Huseyin Naci, *The US Food and Drug Administration's Expedited Approval Programs: Evidentiary Standards, Regulatory Trade-Offs, and Potential Improvements*, 15 CLINICAL TRIALS 219 (2018).

¹⁷ For an example of an “expanded access” program allowing the use of treatments still under review, see Michael J. Joyner, *Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19*, CLINICALTRIALS.GOV (Sept. 2, 2020), <https://clinicaltrials.gov/ct2/show/NCT04338360> [<https://perma.cc/93SU-XPQ7>].

¹⁸ See Pat Basu & Maurie Markman, Opinion, *COVID-19 Is Forcing Us to Rethink Clinical Trials for Cancer Treatments*, SCI. AM. (July 9, 2020), <https://www.scientificamerican.com/article/covid-19-is-forcing-us-to-rethink-clinical-trials-for-cancer-treatments/> [<https://perma.cc/M4YA-68UD>] (discussing existing barriers to participation in clinical trials).

are already seeing barriers excluding people living with disabilities among the thousands of clinical trials of COVID-19 treatments.¹⁹

It is during this most intense need for scarce health care resources that the disparities in healthcare outcomes faced by people living with disabilities is most visibly on display. Commenting on the possibility of having to ration care during the COVID-19 pandemic, Sam Bagenstos warns that triage protocols that exclude people living with disabilities are illegal because they are based on “widespread . . . medical bias against people with disabilities.”²⁰ Oregon has already issued a new law, effective July 7, 2020, that prohibits hospitals from conditioning treatment on the signing of an advanced directive authorizing the withdrawal of life sustaining care.²¹

While today’s situation involving access to COVID-19 trials provides an entry point, the exclusion transcends any particular subject area of research or any specific entity conducting research. This article therefore provides a framework to look at a very serious form of disability discrimination which until quite recently was almost invisible: the near total exclusion of people living with disabilities from research studies. Their exclusion, which mirrors that of much better known excluded populations such as women, children, and African Americans, causes significant harm at a population level because they must live in a world organized around research findings that do not include them.²²

¹⁹ Information about clinical trials is posted in a database managed by the Department of Health and Human Services called ClinicalTrials.gov. It is updated frequently. A recent example is a study of hydroxychloroquine for “COVID-19 infected patients with early moderate and severe disease” that excludes participants who are not able “to take oral pills or . . . use a feeding tube.” LCMC HEALTH, *Treatment in Patients with Suspected or Confirmed COVID-19 with Early Moderate or Severe Disease (RCT)*, CLINICALTRIALS.GOV (Aug. 24, 2020), <https://clinicaltrials.gov/ct2/show/NCT04344444> [<https://perma.cc/THD8-ND23>].

²⁰ Samuel R. Bagenstos, *Who Gets the Ventilator? Disability Discrimination in COVID-19 Medical-Rationing Protocols*, 130 YALE L.J.F. 1, 21 (2020); see also *Preventing Discrimination in the Treatment of COVID-19 Patients: The Illegality of Medical Rationing on the Basis of Disability*, DISABILITY RTS. EDU. & DEF. FUND (Mar. 25, 2020), <https://dredf.org/the-illegality-of-medical-rationing-on-the-basis-of-disability> [<https://perma.cc/W7LT-F6VG>] (warning healthcare providers that they are “subject to the disability nondiscrimination mandates of the ADA” and should be mindful of their obligations when making “decisions about who should or should not receive care”). DREDF also warned “lawmakers and providers of health care . . . of their duty to uphold the civil and human rights of people with disabilities” by not “tak[ing] ‘rationing’ measures.” *Id.*

²¹ OR. REV. STAT. § 127.635.

²² See, e.g., Victoria Shepherd, *An Under-Represented and Underserved Population in Trials: Methodological, Structural, and Systemic Barriers to the Inclusion of Adults Lacking Capacity To Consent*, TRIALS, May 29, 2020, at 2 (“The lack of representation of certain groups in trial populations brings the external validity (the extent to which the results can be generalised to other circumstances or populations) of trials into question, which is even more important when these groups are systematically excluded from those trials.”).

This article is the first to look at the legal implications of this widespread exclusion and argue that exclusion from research needs to be recognized as a serious form of disability discrimination prohibited by the Americans with Disabilities Act (“ADA”).²³ It links exclusion from research with the disparities in healthcare results long recognized in the African-American community and other stigmatized and underserved communities²⁴ in that both phenomena reflect the discrimination and stigma that people living with disabilities still face more than thirty years after the passing of the first federal anti-discrimination statutes.²⁵

Although as of the writing of this article there has never been a reported account of a person living with a disability invoking anti-discrimination laws to gain access to a research study, they have a legal right to do so. That they should be aware of this right is especially important now at a time of a novel virus when access to research studies is so important.

This article proceeds as follows: Part I describes how the exclusion of people with disabilities from research was uncovered and what is known about the situation now; Part II then analyzes how this exclusion causes harm to people living with disabilities and to the larger population of the United States as a whole. Part III begins the process of identifying a legal solution by comparing people living with disabilities’ experience of exclusion with that of other underrepresented populations whose exclusion has been addressed by law. In the process, it identifies the key issue that distinguishes people living with disabilities from other populations in terms of exclusion, which is the concern over the ability of people whose disabling condition affects their ability to give informed consent. Part IV provides an analysis of how the provisions of the Americans with Disabilities Act apply to the different settings in which research is conducted with consideration of the differences between research subject to Title II of the ADA and Title III. Finally, it concludes with an overview of why making research accessible to people living with disabilities is critical to addressing the health and other disparities they experience. It also calls upon all involved parties to be proactive in removing barriers that limit the access of people living with disabilities to research studies early access to drugs.

²³ See Harris, *supra* note 12, at 460–61 (“The ADA, now approaching its twenty-fifth anniversary, sought to address discrimination through greater integration of people with disabilities into society, in part, by increasing their visibility in public spaces. Congress identified stigma, ‘prejudice, [and] antiquated attitudes’ as the primary impediments to full inclusion driving the promulgation of the ADA.”).

²⁴ See Olugbenga Ajilore, *3 Ways to Improve the Outcomes for African Americans in the Rural South*, CTR. FOR AM. PROGRESS (Aug. 6, 2019, 12:01 AM), <https://www.americanprogress.org/issues/economy/reports/2019/08/06/470913/3-ways-improve-outcomes-african-americans-rural-south/> [https://perma.cc/3SSQ-JN95] (considering the impact of systemic racism).

²⁵ Harris, *supra* note 12, at 460–61.

I. EXCLUSION OF PEOPLE WITH DISABILITIES FROM RESEARCH: THE SCOPE OF THE PROBLEM

A. *Who Are People Living With Disabilities?*

Most Americans are, have, or will be living with a condition that impairs our ability to engage in at least some activities essential to our daily lives.²⁶ The number of people living with a disability at any given time depends on the definition used by the entity collecting the data. The Convention on the Rights of Persons with Disabilities defines “Persons with Disabilities” as “those who have long-term physical, mental, intellectual or sensory [such as hearing or vision] impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.”²⁷ The United States Census Bureau reports that 12.7% of the population of the United States (41,089,958 individuals) are living in their communities with a disability.²⁸ These percentages go up with age. The Pew Charitable Trust’s 2015 survey found that “[a]bout half of Americans ages 75 and older (49.8%) reported living with a disability in 2015, as did about a quarter (25.4%) of those 65 to 74.”²⁹ U.S. law prohibiting disability-based discrimination takes a functional approach by considering the effect of a disabling condition while erasing distinctions based on “gender, race, ethnicity, sexual orientation, or social status.”³⁰

²⁶ U.S. DEP’T OF HEALTH & HUMAN SERVS., THE SURGEON GENERAL’S CALL TO ACTION TO IMPROVE THE HEALTH AND WELLNESS OF PERSONS WITH DISABILITIES 1 (2005), https://www.ncbi.nlm.nih.gov/books/NBK44667/pdf/Bookshelf_NBK44667.pdf [<https://perma.cc/P8CA-KVTW>] (explaining that “[m]ost individuals in the United States will experience a disability of some duration at some point in their lives”).

²⁷ United Nations Convention on the Rights of Persons with Disabilities art. 1, Dec. 13, 2006, S. TREATY DOC. NO. 112-7, 2515 U.N.T.S. 72 [hereinafter United Nations].

²⁸ 2019 American Community Survey 1-Year Estimates Subject Tables: Disability Characteristics, U.S. CENSUS BUREAU, <https://data.census.gov/cedsci/table?q=disability&tid=ACST1Y2019.S1810&hidePreview=false> [<https://perma.cc/763D-3PZ7>] (last visited Feb. 2, 2021). The Census Bureau excludes people who are living in hospitals or other medical settings.

²⁹ Kristen Bialik, 7 *Facts About Americans with Disabilities*, PEW RSCH. CTR. (July 27, 2017), <http://www.pewresearch.org/fact-tank/2017/07/27/7-facts-about-americans-with-disabilities/> [<https://perma.cc/R849-CSZK>].

³⁰ See JAMES I. CHARLTON, NOTHING ABOUT US WITHOUT US: DISABILITY OPPRESSION AND EMPOWERMENT 157 (1998) (quoting MICHELLE FINE & ADRIENNE ASCH, WOMEN WITH DISABILITIES: ESSAYS IN PSYCHOLOGY, CULTURE AND POLITICS 3 (1988)) (“To date almost all research on disabled men and women seems simply to assume the irrelevance of gender, race, ethnicity, sexual orientation, or social status. Having a disability presumably eclipses these dimensions of social experience. Even sensitive students of disability . . . have focused on disability as a unitary concept and have taken it to be not merely the ‘master’ status but apparently the exclusive status for disabled people.”).

B. What Makes People With Disabilities A Disparately Impacted Population In Terms Of Health Care Results?

At every stage in maintaining wellness and receiving treatment when facing illness, people living with disabilities face physical and institutional barriers to care.³¹ Their experience echoes the experience of other stigmatized groups who experience worse health outcomes than could be predicted by any other variable such as wealth or geographic location.³² As a result, they receive less care, have less interaction with medical professionals for conditions unrelated to their disability, and have far worse health outcomes.³³ This exclusion exists despite clear protections provided by U.S. civil rights laws prohibiting discrimination in healthcare based on disability.³⁴

³¹ See NAT'L COUNCIL ON DISABILITY, THE CURRENT STATE OF HEALTH CARE FOR PEOPLE WITH DISABILITIES 23 (2009), <https://files.eric.ed.gov/fulltext/ED507726.pdf> [<https://perma.cc/4U3A-UD8D>] (discussing gaps in and barriers to care for people living with disabilities); Lenny Bernstein, *People with Autism, Intellectual Disabilities Fight Bias in Transplants*, WASH. POST (Mar. 4, 2017), https://www.washingtonpost.com/national/health-science/people-with-autism-intellectual-disabilities-fight-bias-in-transplants/2017/03/04/756ff5b8-feb2-11e6-8f41-ea6ed597e4ca_story.html [<https://perma.cc/Q2U2-N5SR>] (detailing the stories of individuals denied healthcare procedures because of their disabilities).

³² See Vickie M. Mays, Susan D. Cochran & Namdi W. Barnes, *Race, Race-Based Discrimination, and Health Outcomes Among African Americans*, 58 ANN. REV. PSYCH. 201, 204 (2007) (reviewing literature documenting the effect of stigma on the health outcomes of African Americans, which are worse than those for white Americans, and concluding that “the causal mechanism linking racial/ethnic minority status and health disadvantage is thought to lie in the harmful effects of chronic experiences with race-based discrimination, both actual and perceived.”). For a discussion of how perceptions of stigmatized populations affect health results, see Valarie K. Blake, *Remedying Stigma-Driven Health Disparities in Sexual Minorities*, 17 HOUS. J. HEALTH L. & POL'Y 183, 200 (2017) (“[T]here is a correlation—though not necessarily causation—between high stigma communities and higher mortality for the majority populations, as well. Data supports increased mortality for all populations in areas that had significant racism, sexism, and other forms of discrimination.”).

³³ This exclusion extends to discrimination in times of public health emergencies. See Wendy F. Hensel & Leslie E. Wolf, *Playing God: The Legality of Plans Denying Scarce Resources to People with Disabilities in Public Health Emergencies*, 63 FLA. L. REV. 719, 723 (2011) (noting that guidelines for providing resources during a potential swine flu epidemic explicitly excluded people “from critical care either because they will need resources for a prolonged period of use, are deemed to have a poor quality of life post-treatment, or otherwise have a limited long-term prognosis as a result of their disabilities”).

³⁴ See Debra T. Berube & Gary C. Norman, *Improving Healthcare Access for People with Disabilities: A Call to Maryland's Leaders*, 45 MD. B.J. 12, 14 (2012) (citing Julia Rothstein & Laura F. Rothstein, *Access to Healthcare: Statutory Overview—Reasonable Accommodation*, in DISABILITIES & THE LAW § 10:3 (4th ed. 2009)) (“If an individual meets the definition of disability, then affirmative requirements under the Americans with Disabilities Act, and its predecessor, the Rehabilitation Act of 1973, provide that individual with rights to accommodation and non-discrimination.”); Elizabeth Pendo, *Reducing Disparities Through Health Care Reform: Disability and Accessible Medical Equipment*, 4

The lack of participation of people with intellectual disabilities in research projects that affect them has long been a concern in the U.K. and Europe, leading to substantial efforts to address the issues raised by the challenges of obtaining informed consent.³⁵ But there has also been more general appreciation that exclusion has extended to people living with disabilities who were fully competent to consent, but who were nevertheless almost completely absent from research on any topic. In 2012, Dr. Shirley M. Moore, who with Dr. Ann S. Williams has made specific recommendations for designing research to be more inclusive for all participants and has become a leading voice in developing universal design for research, published an article noting the absence of people with disabilities in diabetes research.³⁶

The first major article to consider exclusion came from the field of public health.³⁷ Drs. Dianne Rios and Mark Harniss at the Department of Rehabilitation Medicine at the University of Washington in Seattle described their absence as, first, “a civil rights issue,” and second, a breach of “scientific integrity.”³⁸ While evaluating the scope, scale, and significance of the exclusion of people with living disabilities is an ongoing process, there is

UTAH L. REV. 1057, 1065 (2010) (“Although the ADA establishes the necessary foundation for ensuring equal and accessible care for people with disabilities, people with disabilities continue to experience significant barriers to care, including basic preventive health services.”); see also *Disability & Socioeconomic Status*, supra note 12 (citing Mari-Lynn Drainoni, Elizabeth Lee-Hood, Carol Tobias, Sara S. Bachman, Jennifer Andrew & Lisa Maisels, *Cross-Disability Experiences of Barriers to Health-Care Access: Consumer Perspectives*, 17 J. DISABILITY POL’Y STUD. 101, 102 (2006)) (“Research on disability and health care suggests that individuals with a disability experience increased barriers to obtaining health care as a result of accessibility concerns, such as transportation, problems with communication and insurance.”).

³⁵ Victoria Shepherd, Fiona Wood, Richard Griffith, Mark Sheehan & Kerenza Hood, *Protection by Exclusion? The (Lack of) Inclusion of Adults Who Lack Capacity to Consent to Research in Clinical Trials in the UK*, TRIALS, Aug. 5, 2019, at 2–3 (2019) [hereinafter Shepherd et al., *Protection by Exclusion*]. See also Victoria Shepherd, Fiona Wood, Richard Griffith, Mark Sheehan & Kerenza Hood, *Research Involving Adults Lacking Capacity to Consent: A Content Analysis of Participant Information Sheets for Consultees and Legal Representatives in England and Wales*, 20 TRIALS 1, 8–9 (2019) [hereinafter Shepherd et al., *Lacking Capacity*] (analyzing the written information given to proxy decision makers for permission to participate in research trials).

³⁶ Shirley M. Moore, *Scientific Reasons for Including Persons with Disabilities in Clinical and Translational Diabetes Research*, 6 J. DIABETES SCI. & TECH. 236 (2012); see also Ann S. Williams & Shirley M. Moore, *Universal Design of Research: Inclusion of Persons with Disabilities in Mainstream Biomedical Studies*, 3 SCI. TRANSLATIONAL MED. 1, 3 (2011) (“We propose [Universal Design of Research]—defined as the design of research so that all people can be included as potential participants, to the greatest extent possible, without the need for adaptation or specialized design—as a new model for research.”).

³⁷ Dianne Rios, Susan Magasi, Catherine Novak & Mark Harniss, *Conducting Accessible Research: Including People with Disabilities in Public Health, Epidemiological, and Outcomes Studies*, 106 AM. J. PUB. HEALTH 2137, 2137–38 (2016).

³⁸ *Id.* at 2143.

enough evidence to consider the meaning of this exclusion, the reasons behind it, and the path forward using legal tools to begin addressing a public health calamity that will require considerable change in how research is funded and conducted in the United States.³⁹

Not surprisingly, the health outcome disparities are even greater for people with disabilities who also belong to other groups that experience disparately poor health outcomes such as African Americans, Hispanics/Latinos, American Indians, low socioeconomic status populations, rural populations, and members of the LGBTQ community.⁴⁰ The harm is intensified by the fact that members of this community are themselves more likely to also be living with mobility and other forms of disability that negatively impact healthcare outcomes.⁴¹

C. Documenting Exclusion from Research

As with so many things related to disability-based discrimination, the challenge faced in documenting exclusion from research is that it has for so long been invisible to researchers—although not to the people living with disabilities themselves.⁴² Responding to the FDA’s 2013 call for comments

³⁹ See *Director’s Message, Sexual and Gender Minorities Formally Designated as a Health Disparity Population for Research Purposes*, NAT’L INST. ON MINORITY HEALTH & HEALTH DISPARITIES (Oct. 6, 2016), https://www.nimhd.nih.gov/about/directors-corner/messages/message_10-06-16.html [<https://perma.cc/NCZ2-VTUD>] (“Mounting evidence indicates that SGM populations have less access to health care and higher burdens of certain diseases, such as depression, cancer, and HIV/AIDS. But the extent and causes of health disparities are not fully understood, and research on how to close these gaps is lacking.”).

⁴⁰ See generally 1 NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., NIH HEALTH DISPARITIES STRATEGIC PLAN: FISCAL YEARS 2004–2008 (2004), https://www.nimhd.nih.gov/docs/2004_2008_strategic_plan_vol1.pdf [<https://perma.cc/4ZSM-YQLN>] (discussing healthcare disparities in underserved populations); OFF. OF MINORITY HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., COMPENDIUM OF FEDERAL DATASETS ADDRESSING HEALTH DISPARITIES (2019), https://www.minorityhealth.hhs.gov/assets/pdf/2019%20IHEC%20Data%20Compendium_FullDocument_RegularFormat%20-%202022-6-20-508-2.pdf [<https://perma.cc/8RBZ-2QVE>] (compiling federal datasets showing disparities in healthcare).

⁴¹ SILVIA YEE, DISABILITY RTS. EDUC. & DEF. FUND, HEALTH AND HEALTH CARE DISPARITIES AMONG PEOPLE WITH DISABILITIES (2011) (citing HEALTH & HUM. SERVS. ADVISORY COMM. ON MINORITY HEALTH, ASSURING HEALTH EQUITY FOR MINORITY PERSONS WITH DISABILITIES: A STATEMENT OF PRINCIPLES AND RECOMMENDATIONS 11 (2011)), <https://dredf.org/healthcare/Health-and-Health-Care-Disparities-Among-People-with-Disabilities.pdf> [<https://perma.cc/VPP9-XSP6>] (“Aside from the public health issues that most racial/ ethnic minorities face, minorities with disabilities experience additional disparities in health, prejudice, discrimination, economic barriers, and difficulties accessing care as a result of their disability—in effect, they face a “double burden.”).

⁴² See, e.g., Michelle Hardy, *When People Talk About Me as If I’m Not There Because I Have*

on a plan to increase information about “how new drugs and devices work in people with disabilities,” the Disability Rights Education & Defense Fund (DREDF) wrote that it was “difficult to assess or critique” the plan because “information concerning disability is routinely excluded from clinical research in general.”⁴³ Therefore, “[s]cientific evidence is lacking about effective treatments for people with disabilities . . . because they are routinely excluded from clinical trials.”⁴⁴ If you are looking for it, information about the exclusion of people living with specific kinds of disabilities is scattered throughout the scientific, medical, and social science literature.⁴⁵ But until very recently, evidence of exclusion of people with disabilities came to light only when consumers of research, such as physicians, psychologists, and teachers, who looking for evidence-based interventions were surprised enough to find nothing and wrote up that result.⁴⁶

For example, Dr. Maurice Feldman took a random sample of research studies from “two well-respected, high profile” child development journals from 1996 to 2010 looking for the inclusion of children with disabilities as subjects.⁴⁷ He reported that he and his team “found that most studies probably did not include children with disabilities” even though they “represent

a Disability, MIGHTY (Aug. 17, 2016), <https://themighty.com/2016/08/being-treated-as-invisible-because-i-have-a-disability/> [<https://perma.cc/9Q79-A4NE>] (recounting an incident in an airport when a passenger seeking to cut ahead of the author at the security line asked a stranger standing nearby if it was okay to cut in front of “her”). The author of this article explained that people with disabilities being treated as invisible

actually happens quite often to people with visible disabilities. I don’t know if it’s because people are scared to talk to us because we’re a bit different, or if they assume we might not be able to comprehend situations or speak to people. Or maybe it’s a completely different reason I haven’t yet cracked, but it is *always* unsettling to realize that people talk about you when you are right there, without seeming to acknowledge your presence.

Id.

⁴³ Disability Rights Educ. & Def. Fund, Comment Letter on Food and Drug Administration’s Report: Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products (Nov. 20, 2013) <https://dredf.org/wp-content/uploads/2013/11/FDA-demographic-data-disability-response-11-20-13-Final.pdf> [<https://perma.cc/VP P9-XSP6>] [hereinafter DREDF Comment Letter].

⁴⁴ *Id.*

⁴⁵ For an example of studies looking at the exclusion of people with disabilities from research on specific topics, see Monika Mitra, Susan L. Parish, Karen M. Clements, Xiaohui Cui & Hafsatou Diop, *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, 48 AM. J. PREVENTIVE MED. 300 (2015).

⁴⁶ See Maurice A. Feldman, Susan M. Battin, Olivia A. Shaw & Ruth Luckasson, *Inclusion of Children with Disabilities in Mainstream Child Development Research*, 28 DISABILITY & SOC’Y 997, 998 (2013) (“The precise prevalence of children with disabilities in current research is unknown, but is considered under-representative.”).

⁴⁷ *Id.* at 1000.

approximately 15% of children.”⁴⁸ In another study, a Canadian research team sought information about pregnancy outcomes among women with intellectual and developmental disabilities. After coming up dry, they dug deeper and found that “[t]here is no current, valid estimate of the yearly fertility rate in women with [Intellectual and Developmental Disabilities].”⁴⁹

As Dr. Maurice Feldman explains, because “[t]he application of child development research has led to innovative and effective school, community and health services, and impacted government policies and funding [s]ystematic exclusion of children with disabilities from research . . . may limit beneficence to them.”⁵⁰

Concerned about the lack of information about how to develop health promotion programs for people with disabilities, a team led by Dr. James Rimmer found that “[t]he vast majority of health promotion research targets populations who do not have a disability.”⁵¹

Now that exclusion of people with disabilities is part of the larger conversation and more researchers are looking for it, evidence of exclusion is increasing. A newsletter describing new brain imaging studies noted that “even though nonverbal or minimally verbal people who have autism spectrum disorder (ASD) make up between 25 and 30 percent of the total autistic population, almost no studies have been done focusing on this group and their particular needs.”⁵² Similarly, researchers looking for evidence-based research on the effectiveness of different kinds of therapies for anxiety

⁴⁸ *Id.* at 1004. The study found an overall exclusion rate of 89.9%. *Id.* at 1003.

⁴⁹ See Hilary K. Brown, Yona Lunskey, Andrew S. Wilton, Virginie Cobigo & Simone N. Vigod, *Pregnancy in Women with Intellectual and Developmental Disabilities*, 38 J. OBSTETRICS & GYNAECOLOGY CAN. 9, 10, 13 (2016) (finding as a preliminary matter that “[t]here is no current, valid estimate of the yearly fertility rate in women with IDD” and that, based on research they conducted, women with intellectual disabilities used medication at high rates during pregnancy and were more likely to be young, live in poverty, and suffer from epilepsy, obesity, and mental health problems).

⁵⁰ Feldman et al., *supra* note 46, at 998.

⁵¹ James H. Rimmer, Kerri A. Vanderbom, Linda G. Bandini, Charles E. Drum, Karen Luken, Yolanda Suarez-Balcazar & Ian D. Graham, *GRAIDs: A Framework for Closing the Gap in the Availability of Health Promotion Programs and Interventions for People with Disabilities* IMPLEMENTATION SCI., Aug. 14, 2014, at 1, 2. This study proposes new research designs in order to increase the number of people with disabilities in programs and interventions as well as research. *Id.* at 6–7.

⁵² *Brain Imaging Reveals Mechanisms Underlying Auditory Processing in Nonverbal Children with Autism*, NEWS MED. LIFE SCI. (Sept. 18, 2019), <https://www.news-medical.net/news/20190918/Brain-imaging-reveals-mechanisms-underlying-auditory-processing-in-nonverbal-children-with-autism.aspx> [<https://perma.cc/CFQ4-BV7Q>]; see also Timothy P.L. Roberts, Junko Matsuzaki, Lisa Blaskey, Luke Bloy, J. Christopher Edgar, Mina Kim, Matthew Ku, Emily S. Kushner & David Embick, *Delayed M50/M100 Evoked Response Component Latency in Minimally Verbal/Nonverbal Children Who Have Autism Spectrum Disorder*, MOLECULAR AUTISM, Aug. 15, 2019, at 1, 2 (discussing the frequent exclusion of nonverbal and minimally verbal people who have ASD from brain imaging research).

and depression for people with disabilities reviewed 18,949 papers but found “only six [randomized control trials] on the management of mental ill health of any kind for people with mild intellectual disabilities, and all of these were small, feasibility or pilot studies.”⁵³ They concluded that “randomised controlled trials of interventions to manage mental ill health in adults with intellectual disabilities need to be a research priority.”⁵⁴

Despite the strong calls by Dr. Rios and her team for “[f]ederal funding agencies” to “emphasize the importance of inclusion of people with disabilities”⁵⁵ it took the need to diversify research populations in order to advance the developing field of personal or precision medicine.

D. The Role of Precision Medicine in Encouraging Diverse Participation in Research

The growing importance of using genetic information to tailor medical treatment has been a driving force in calling attention to the exclusion of entire populations from participation in research and has led to today’s strong interest in seeking out a more diverse research population that includes people living with disabilities.⁵⁶ In his January 20, 2015 State of the Union Address, President Obama announced his intention to launch a Precision Medicine Initiative to use advances in genetics to “bring us closer to curing diseases like cancer and diabetes.”⁵⁷ This initiative was the product of rapid advances in science following the launch of the Human Genome Project (HGP) and its achievement of mapping the human genome.⁵⁸ In particular, technological advances that made it possible to quickly and

⁵³ Martin Osugo & Sally-Ann Cooper, *Interventions for Adults with Mild Intellectual Disabilities and Mental Ill-Health: A Systematic Review*, 60 J. INTELL. DISABILITY RSCH. 615, 619 (2016).

⁵⁴ *Id.* at 620.

⁵⁵ Rios et al., *supra* note 37, at 2143.

⁵⁶ See generally Maya Sabatello, Lou Ann Blake, Audrey Chao, Arielle Silverman, Ronit Ovadia Mazzoni, Yuan Zhang, Ying Chen & Paul S. Appelbaum, *Including the Blind Community in Precision Medicine Research: Findings from a National Survey and Recommendations*, 21 GENETICS MED. 2631 (2019) (discussing the obstacles to inclusion of blind people in research).

⁵⁷ Address Before a Joint Session of the Congress on the State of the Union, 2015 DAILY COMP. PRES. DOC. 1 (Jan. 20, 2015).

⁵⁸ For a historical overview of the development of the Human Genome Project, the significance of its achievement in mapping the human genome, and the resulting creation of the field of precision medicine see Leroy Hood & Lee Rowen, *The Human Genome Project: Big Science Transforms Biology and Medicine*, GENOME MED., Sept. 13, 2013, at 1. See also Jon Heggie, *Genomics: A Revolution in Health Care?*, NAT’L GEOGRAPHIC (Feb. 20, 2019), <https://www.nationalgeographic.com/science/2019/02/partner-content-genomics-health-care> [<https://perma.cc/35WS-2EQW>] (exploring the linkages between human genome research and pharmacological innovation).

inexpensively sequence individual genomes supported the development of algorithms that could take the data generated and identify the relationships between specific groupings of genes, markers, and responses to medications.⁵⁹ While physicians have long observed that men and women⁶⁰ or people from different regions⁶¹ have very different reactions to the same medications, without the ability to draw comparisons on the genetic level, it was difficult to translate these observations into actionable treatment.⁶² But it was not until the development of what is now called pharmacogenetics that it became possible to select the most effective medical treatments for individuals who were members of a population sharing specific genetic markers.⁶³ As understanding of the role that genetics plays in both the likelihood of an individual having a disease or condition⁶⁴ and an individual's responses to medical treatment⁶⁵ grows, the call for more diverse research populations has become even more urgent.⁶⁶

⁵⁹ For further discussion on advances in precision medicine, see *The Promise of Precision Medicine*, NAT'L INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/nih-turning-discovery-into-health/promise-precision-medicine> [<https://perma.cc/V23G-P7TN>] (last visited Feb. 12, 2020).

⁶⁰ Heather P. Whitley, *Sex-Based Differences in Drug Activity*, 11 AM. FAM. PHYSICIAN 1254, 1254 (2009) ("Sex-related differences . . . have important implications for drug activity . . .").

⁶¹ Kunioto Asano, Yoshiaki Uyama & Masahiro Tohkin, *Factors Affecting Drug-Development Strategies in Asian Global Clinical Trials for Drug Approval in Japan*, 11 CLINICAL & TRANSLATIONAL SCI. 182, 187–88 (assessing the impact of both genetic and cultural "ethnic differences" between Asian and Caucasian populations on Asian clinical drug trials).

⁶² See CTRS. FOR DISEASE CONTROL & PREVENTION, *Perspectives in Disease Prevention and Health Promotion Report of the Secretary's Task Force on Black and Minority Health*, 35 MORBIDITY & MORTALITY WKLY. REP. 109 (1986), <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000688.htm> [<https://perma.cc/75CH-T725>] (reporting on the Task Force's progress since its establishment in 1984 "in response to the national paradox of steady improvement in overall health, with substantial inequities in the health of U.S. minorities").

⁶³ See Heggie, *supra* note 58 (detailing how pharmacogenomics has transformed the traditionally generalist approach to drug development).

⁶⁴ The work of identifying genetic links to disease is ongoing. See, e.g., Nick Shrine et al., *Moderate-to-Severe Asthma in Individuals of European Ancestry: A Genome-Wide Association Study*, 7 LANCET RESPIRATORY MED. 20, 29–32 (2019) (finding three new genetic asthma signals in the "largest genetic-association study of moderate-to-severe asthma to date").

⁶⁵ Jaime Crespo, *A Genetic Cause for Iron Deficiency*, HARV. GAZETTE (Apr. 9, 2008), <https://news.harvard.edu/gazette/story/2008/04/a-genetic-cause-for-iron-deficiency> [<https://perma.cc/3MHH-QDMP>] (describing how differences in individuals' blood-iron levels affect physiological functioning of people with different genetic material); Maulana Bachtiar & Caroline G.L. Lee, *Genetics of Population Differences in Drug Response*, 1 CURRENT GENETIC MED. REPS. 162, 163 (2013) ("5-Fluorouracil, a commonly used cancer chemotherapeutic drug, has been frequently reported to exhibit differences in drug response among different populations.").

⁶⁶ Katherine J. Wu, *Lack of Diversity in Genetic Research Could Be Costing Us Our Health*, PBS: NOVA (Mar. 21, 2019), <https://www.pbs.org/wgbh/nova/article/lack-diversity-genetic->

When it became increasingly apparent that there were very few “one on one” correlations between the presence of a particular gene and the response to a medication, the biomedical research community’s need for a much more diverse study population took on a greater urgency.⁶⁷

Housed at NIH, the genome sequencing team came together quickly. By November 2015, it published a report outlining a plan for developing “a large research cohort of one million or more Americans.”⁶⁸ This large a group was needed, the task force explained, because past practices of “[r]igorous evaluation of the safety and efficacy of new preventive and therapeutic strategies” were “based on the expected response of a ‘typical’ patient.”⁶⁹ With a growing understanding of genetics, however, “it is clear that individual patients can have markedly variable responses to therapy, ranging from highly efficacious outcome, to no effect, to deleterious outcome.”⁷⁰ Soon afterwards, the Working Group realized that the issue wasn’t just recruiting a larger number of research subjects, but a more diverse one. As a result, they began a process of building “cultural competence” into the recruiting process in “recognition that research to improve health outcomes requires culturally sensitive research designs and collaboration with racial/ethnic communities.”⁷¹ It was in the development of this process, that

research-could-be-costing-us-our-health/ [https://perma.cc/S7K3-C5VL] (“‘Diversity issues aren’t just moral, but also scientific,’ says Alicia Martin, a geneticist at the Broad Institute of MIT and Harvard. ‘There’s a staggering disparity that we haven’t grappled with that’s going to affect clinical tests or other parts of precision medicine.’”).

⁶⁷ See, e.g., Raj Kurupati, Andrew Kossenkov, Larissa Haut, Senthil Kannan, Zhiquan Xiang, Yan Li, Susan Doyle, Qin Liu, Kenneth Schmader, Louise Showe & Hildegund Ertl, *Race-Related Differences in Antibody Responses to the Inactivated Influenza Vaccine Are Linked to Distinct Pre-Vaccination Gene Expression Profiles in Blood*, 7 ONCOTARGET 62898, 62905 (2016) (confirming previous studies’ findings that “ethnicity can influence immune responses to vaccination”).

⁶⁸ PRECISION MED. INITIATIVE WORKING GRP., NAT’L INSTS. OF HEALTH, THE PRECISION MEDICINE INITIATIVE COHORT PROGRAM—BUILDING A RESEARCH FOUNDATION FOR 21ST CENTURY MEDICINE 1 (2015), <https://acd.od.nih.gov/documents/reports/DRAFT-PMI-WG-Report-9-11-2015-508.pdf> [https://perma.cc/N429-UECT].

⁶⁹ *Id.* at 6.

⁷⁰ *Id.* (“The roots of this variability likely include unrecognized differences in disease pathophysiology, environmental exposures, social and behavioral factors, and genetic factors.”); see also Chanita Hughes Halbert, Jasmine McDonald, Susan Vadaparampil, LaShanta Rice & Melanie Jefferson, *Conducting Precision Medicine Research with African Americans*, PLOS ONE, July 21, 2016, at 2 (“Research is now being conducted to identify and understand barriers and facilitators to African American participation in genomics research . . .”).

⁷¹ Maya Sabatello, *Cultivating Inclusivity in Precision Medicine Research: Disability, Diversity, and Cultural Competence*, 10 J. COMMUNITY GENETICS 363, 363–64 (2019) (“Unlike previous NIH guidelines that only urged researchers to develop appropriate and culturally sensitive outreach programs, the All of Us Research Program has explicitly recognized that enrollment and retention of participants entails respectful and culturally appropriate engagement with them.” (citation omitted)).

the exclusion of people with disabilities identified by Dr. Rios and her team caught the attention of researchers developing outreach programs for underserved populations.⁷² After decades of scarce or any notice, article after article was published all telling the same story: that people living with disabilities were a larger portion of the U.S. population than the previously identified under-researched groups and that they had never been the subject of “comprehensive” genetic research.⁷³

E. Recognition of Exclusion by Private Funders

Another consequence of the exclusion of people living with disabilities from research is a pervasive lack of information about their needs as a population apart from direct disability services.⁷⁴ In a 2019 open letter to all private funders, the leaders of the Robert Wood Johnson and Ford Foundations announced the formation of the “Presidents’ Council on Disability Inclusion in Philanthropy” to address, collectively, the absence of programming targeting the needs of people with disabilities.⁷⁵ At the same time, nonprofits are realizing that not only are they violating their moral principles in excluding people with disabilities, they are also violating the law. For example, the Chicago Community Trust has issued a 123-page *ADA Compliance Guide for Nonprofits* which begins with the exhortation that “[a]ll nonprofits should review and evaluate their obligations and renew their

⁷² See *id.* at 365 (citing Rios et al., *supra* note 37) (“Comprehensive data about participation of people with disabilities in PMR are not available. However, there are reasons to believe that, without appropriate strategies in place, persons with disabilities will not be well represented in PMR (similar to most mainstream health research).”).

⁷³ See generally *id.*; Sabatello et al., *supra* note 56.

⁷⁴ See Sabatello, *supra* note 71, at 367 (“Insufficient knowledge about how to design PM studies that are accessible to people with a range of abilities (‘universal design’) and that offer accommodations may also lead to incorrect presumptions”); Darren Walker, *Ignorance is the Enemy Within: On the Power of Our Privilege, and the Privilege of Our Power*, FORD FOUND. (Sept. 12, 2016), <https://www.fordfoundation.org/just-matters/equal-change-blog/posts/ignorance-is-the-enemy-within-on-the-power-of-our-privilege-and-the-privilege-of-our-power/> [<https://perma.cc/3CQS-2H2D>] (describing how, as President of the Ford Foundation, Darren Walker did not realize that his initiative to “disrupt[]” “entrenched inequality of all kinds” failed to mention “a huge community: the more than one billion people around the world who live with one form of disability or another” and who “face harsh inequalities” that regularly intersect[] with other forms of inequality we already address in our work”).

⁷⁵ Rich Besser & Darren Walker, *Real Equity Means Including People with Disabilities in Philanthropy*, CHRON. PHILANTHROPY (Apr. 2, 2019), <https://www.philanthropy.com/article/No-Equity-Without-Everyone-/245991> [<https://perma.cc/55ZM-Q7V6>] (noting recent criticism and stating that for “[t]oo long, philanthropy has operated under the premise that ‘disability is a worthy cause, but it isn’t ours.’ But relegating disability-related issues to a niche grant-making area or, worse, ignoring people with disabilities completely is no longer acceptable in philanthropy.”).

efforts to offer full and equal access to people with disabilities in light of the new requirements.”⁷⁶

F. Finding Evidence of Harm from Exclusion from the Experience of Other Excluded Populations

Unfortunately, the exclusion of an entire population from participation in research is an all too familiar story in the United States. There is extensive evidence of the exclusion of and resulting harm to other populations, such as African-Americans,⁷⁷ the elderly,⁷⁸ pregnant women,⁷⁹

⁷⁶ Irene Bowen, CHIC. CMTY TR., RENEWING THE COMMITMENT: AN ADA COMPLIANCE GUIDE FOR NONPROFITS 1 (2015), <http://www.cct.org/wp-content/uploads/2015/08/2015ADAComplianceGuide.pdf> [<https://perma.cc/UX9H-M9DE>].

⁷⁷ See generally Ruqaiijah Yearby, *Exploitation in Medical Research: The Enduring Legacy of the Tuskegee Syphilis Study*, 67 CASE W. RES. L. REV. 1171 (2017) (discussing the Tuskegee Syphilis Study); Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221 (2003) (discussing the exclusion of racial and ethnic minorities from medical research studies); Heather R. Romero, Kathleen A. Welsh-Bohmer, Lisa P. Gwyther, Henry L. Edmonds, Brenda L. Plassman, Cassandra M. Germain, Michelle McCart, Kathleen M. Hayden, Carl Pieper & Allen D. Roses, *Community Engagement in Diverse Populations for Alzheimer's Disease Prevention Trials*, 28 ALZHEIMER DISEASE & ASSOCIATED DISORDERS 269, 270 (2014) (discussing the challenges of recruiting healthy volunteers for Alzheimer's studies, researchers at Duke noted that “[i]t is well known that clinical trials for AD do not typically include large numbers of African-Americans (AAs) for a variety of complex historical and societal reasons.”).

⁷⁸ See Vivek H. Murthy, Harlan M. Krumholz & Cary P. Gross, *Participation in Cancer Clinical Trials: Race-, Sex-, and Age-Based Disparities*, 291 JAMA 2720, 2721 (2004) (“Although elderly patients represent approximately two thirds of cancer patients, they account for only 25% to 30% of clinical trial participants.”).

⁷⁹ See Alison Kodjak, *Research Gaps Leave Doctors Guessing About Treatments for Pregnant Women*, NPR: SHOTS (Dec. 10, 2018, 3:26 PM), <https://www.npr.org/sections/health-shots/2018/12/10/673897043/research-gaps-leave-doctors-guessing-about-treatments-for-pregnant-women> [<https://perma.cc/24P5-V7MD>] (quoting Jacqueline Wolf, describing the irony of excluding pregnant women from clinical trials: “Because researchers are hardly ever permitted to conduct trials on pregnant women, we end up experimenting on pregnant women all the time, because we can't accumulate a solid fund of evidence . . . we just stick with the old standards, or we introduce new things without doing trials on them.”). See generally Barbara A. Noah, *The Inclusion of Pregnant Women in Clinical Research*, 7 ST. LOUIS U. J. HEALTH L. & POL'Y 353 (2014) (discussing the need for drug companies to include pregnant patients in clinical research trials). Unfortunately, this same exclusion of pregnant women from research trials has persisted in the testing of new COVID-19 vaccines. See Paul T. Heath, Kirsty Le Doare & Asma Khalil, *Inclusion of Pregnant Women in COVID-19 Vaccine Development*, 20 LANCET 1007, 1007 (Aug. 11, 2020), [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30638-1](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30638-1) [<https://perma.cc/T22R-BCZ5>] (“A particular consideration is that for many of the vaccine candidates and platforms being actively considered . . . no trials have been done in pregnant women.”)

children,⁸⁰ Hispanics,⁸¹ women as a population,⁸² and incarcerated individuals.⁸³ One of the first substantial public discussions of the harm of excluding populations came from Professor Rebecca Dresser's 1992 article criticizing the practice of limiting medical research subjects to young white men and noting that the practice "resulted in significant gaps in [our] knowledge' of diseases that affect both men and women."⁸⁴

⁸⁰ For an overview of both the historic exclusion of children from clinical drug trials and the FDA and Congress' efforts to increase their participation, see Holly Fernandez Lynch, *Give Them What They Want?: The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act*, 16 ANNALS HEALTH L. 79 (2007). This exclusion of children from clinical trials persists in the initial trials of vaccines to prevent COVID-19. See Denise Grady, *Moderna Plans to Begin Testing Its Coronavirus Vaccine in Children*, N.Y. TIMES (Feb. 12, 2021), <https://www.nytimes.com/2020/12/02/health/Covid-Moderna-vaccine-children.html> [<https://perma.cc/Y88X-LL7J>] (noting that, at least as of December 2020, Moderna's vaccine had not yet been studied in children); Jared S. Hopkins, *Covid-19 Vaccine Makers Turn Toward Testing Children*, WALL STREET J. (Dec. 11, 2020, 7:00 am), <https://www.wsj.com/articles/covid-19-vaccine-makers-turn-toward-testing-children-11607688001> [<https://perma.cc/M2GS-SU9E>] (mentioning the "omission of children in U.S. vaccine trials").

⁸¹ See Paula Andalo, *Latinos Left Out of Clinical Trials . . . and Possible Cures*, USA TODAY (July 24, 2017, 3:16 PM), <https://www.usatoday.com/story/news/2017/07/24/kaiser-latinos-left-out-clinical-trials-and-possible-cures/103956714/> [<https://perma.cc/L8MG-4TEG>] (noting that Hispanics are often underrepresented in clinical trials).

⁸² See, e.g., Nathaniel M. Robbins & James L. Bernat, *Minority Representation in Migraine Treatment Trials*, 57 HEADACHE 525, 530 (2017) ("Migraine clinical trials uniformly report the proportion of women in the trial, but only two-thirds report the racial composition of the study sample. No trials analyze efficacy or safety results by race or sex."); John J. Whyte, *FDA Drug Trials Snapshots and Diversity When Testing New Drugs*, CASE COMPREHENSIVE CANCER CTR. (May 8, 2017), <https://case.edu/cancer/about-us/news/fda-drug-trials-snapshots-and-diversity-when-testing-new-drugs> [<https://perma.cc/XFQ2-7EQL>] ("For instance, women are often prescribed only half the dose that men take of the sleep medication, Ambien (zolpidem). Race and ethnicity also make a difference. One type of drug commonly used to treat high blood pressure, angiotensin-converting enzyme (ACE) inhibitors, has been shown to be less effective in African American patients than in white patients.").

⁸³ See generally Allen M. Hornblum, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMESBURG PRISON* (1998) (recounting abuses suffered at a specific prison); Sharona Hoffman, *Beneficial and Unusual Punishment: An Argument in Support of Prisoner Participation in Clinical Trials*, 33 IND. L. REV. 475 (2000) (recounting the abuse of prisoners forced to participate in biomedical experimentation, but arguing that prisoners should be included in biomedical research with adequate protections); Lawrence O. Gostin, *Biomedical Research Involving Prisoners: Ethical Values and Legal Regulation*, 297 JAMA 737, 739 (2007) (considering the risks and potential benefits of including prisoners in trials). For a discussion on COVID-19 trials on prisoners see Nayanah Siva, *Experts Call to Include Prisons in COVID-19 Vaccine Plans*, 396 LANCET, 1870, 1870 (2020).

⁸⁴ Rebecca Dresser, *Wanted: Single, White Male for Medical Research*, 22 HASTINGS CTR. REP. 24, 24 (1992); see also Katherine A. Liu & Natalie A. Dipietro Mager, *Women's Involvement in Clinical Trials: Historical Perspective and Future Implications*, 14 PHARMACY PRAC. 708, 709 (2016) ("[I]n previous decades the consideration and inclusion of men overshadowed women in clinical research design and conduct.").

II. HARM CAUSED BY EXCLUSION FROM RESEARCH

There are many negative consequences to a population being excluded from research studies, some general to all excluded populations and some particular to their characteristics. As DREDF explains: “The failure to include or even identify people with disabilities when providers and health care delivery systems are increasingly held to ‘evidence-based medicine’ standards means that individuals with disabilities face procedural delays and barriers because there are few scientifically validated or administratively ‘pre-authorized’ treatments for people with disabilities.”⁸⁵ It specified that “[t]here is a dearth of scientifically validated information about how people with various disabilities respond to common, leading, or cutting edge treatments, whether they are medical, mental or behavioral health, or preventive programs for smoking cessation or weight loss.”⁸⁶

A. Population-Based Harm Caused to People with Disabilities by Exclusion from Research

Because they are not included in the data gathering process, exclusion of people living with disabilities from research causes considerable harm to both the population living with disabilities as a whole and sub-populations of those living with specific disabling conditions.

1. Harm from lack of information about conditions that affect the general population but may impact people living with disabilities differently

As a population, people living with disabilities are subject to the same illnesses and conditions that affect the general population, such as heart disease, but may be affected differently or may respond differently to treatment.⁸⁷ There are also examples of gaps in knowledge about behavioral or educational issues specific to people living with disabilities.⁸⁸

⁸⁵ DREDF Comment Letter, *supra* note 43.

⁸⁶ *Id.*

⁸⁷ See Beth Levine, *Statins Are Safe to Use for Heart Protection in People with Rheumatoid Arthritis*, EVERYDAY HEALTH (Apr. 15, 2019), <https://www.everydayhealth.com/rheumatoid-arthritis/rheumatoid-arthritis-statins-are-safe-heart-protection/> [https://perma.cc/R69H-EZ6B] (reporting on a study of people with rheumatoid arthritis who take statins for heart disease).

⁸⁸ Although the focus of this article is exclusion of people living with disabilities from research not specifically related to their disabling condition, it is important to recognize that harm also comes from lack of research about their disabling condition. For example, the National Institute of Dental and Craniofacial Research reports a long list of health challenges faced by people with developmental disabilities “such as autism, cerebral palsy, Down syndrome, and other cognitive

One of the most important questions raised in looking at exclusion from research is whether it causes disparate health outcomes or whether those phenomena are correlative, in that they have a common cause. Dr. Dianne Rios echoes this concern writing that because “people with disabilities [are] one of the largest minority groups in the country,” their exclusion from “research seriously limits the application of research findings for a significant patient population.”⁸⁹

One of the ways that people with disabilities experience harm as a population is being excluded from research related to conditions that may affect them differently depending on the specific impact of their disabling conditions. For example, finding that women with developmental disabilities experienced worse health outcomes, a research team from Canada concluded that “[o]ur findings suggest an urgent need to focus on reproductive and perinatal health in women with IDD and to develop appropriate services and policies to support their needs.”⁹⁰

2. Harm from lack of knowledge specific to the disabling condition

There are several different ways that a person living with a disability could be harmed by exclusion from a trial specific to their own disabling condition. The first is the direct failure to conduct the trial at all. The second is exclusion from a trial specific to their condition, but containing so many conditions for participation that most people are ineligible. For example, often trials are restricted to individuals with only one condition.⁹¹

disabilities” that “create challenges in accomplishing daily activities” which “often require a special approach to dental care.” *Developmental Disabilities & Oral Health*, NAT’L INST. OF DENTAL & CRANIOFACIAL RSCH. (Oct. 2020), <https://www.nidcr.nih.gov/health-info/developmental-disabilities/more-info> [<https://perma.cc/22SD-4KXN>].

⁸⁹ Rios et al., *supra* note 37, at 2137 (citing Feldman et al., *supra* note 46, at 1003 (noting an exclusion rate of 89.9%)).

⁹⁰ Brown et al., *supra* note 49, at 15. For example studies of interventions to address a harmful behavior prevalent among people with disabilities, see Teresa Iacono & Vanessa Murray, *Issues of Informed Consent in Conducting Medical Research Involving People with Intellectual Disability*, 16 J. APPLIED RSCH. INTELL. DISABILITIES 41 (2003); Bradley Crook, Rose Tomlins, Ann Bancroft & Laura Ogi, ‘So Often They Do Not Get Recruited’: *Exploring Service User and Staff Perspectives on Participation in Learning Disability Research and the Barriers that Inhibit It*, 44 BRIT. J. LEARNING DISABILITIES 130 (2016).

⁹¹ For example, a study on the genetic and physical characteristics of individuals with a genetic brain disorder that can interfere with intellectual development, Rett Syndrome, could also be discriminatory if its protocol excludes participation of people with Rett Syndrome who have other disabling conditions. See Alan K. Percy, *Genetic and Physical Characteristics of Rett Syndrome*, CLINICALTRIALS.GOV (Mar. 16, 2017), <https://clinicaltrials.gov/ct2/show/NCT00299312> [<https://perma.cc/U8BK-FA44>] (describing a study on Rett Syndrome treatment excluding individuals unable to travel to study sites).

3. Dignitary harm

Exclusion from research is also exclusion from full participation in society.⁹² As the Supreme Court held in *Olmstead*, it is not enough to avoid discrimination; a government program must not act in a way that “perpetuates unwarranted assumptions” that people with disabilities cannot “participat[e] in community life.”⁹³ This kind of rights-based language is reflected in the Irish National Disability Authority’s (NDA) 2002 guidelines on how to foster inclusion.⁹⁴ For example, the National Institutes of Health in explaining its mission to support biomedical research explains that “clinical research” is a “social good.”⁹⁵ The United Nation’s Convention on the Rights of People with Disabilities has identified access to research as a strategic priority and a human right that should be made equally available to people living with disabilities.⁹⁶

B. Harm of Exclusion from Research That Provides Individual Participants a Direct Benefit: The Case of Clinical Trials

The lack of approved drugs to treat COVID-19 or vaccines to protect it creates an urgency to gain access to clinical trials reminiscent of the early days of the AIDS epidemic. Using the slogan “Drugs into Bodies,” the grass roots organization ACT UP argued that “with a new epidemic disease such as AIDS, testing experimental new therapies is itself a form of health care and that access to health care must be everyone’s right.”⁹⁷ But in the days

⁹² Thank you to Professor Jacqueline Fox of South Carolina University School of Law for pointing out this form of harm.

⁹³ *Olmstead v. L.C. ex rel. Zimring*, 527 U.S. 581, 600 (1999).

⁹⁴ NAT’L DISABILITY AUTH., GUIDELINES FOR INCLUDING PEOPLE WITH DISABILITIES IN RESEARCH 8 (2002), <http://nda.ie/nda-files/Guidelines-for-Including-People-with-Disabilities-in-Research.pdf> [<https://perma.cc/EB3E-36FK>] (discussing guidelines for effectively including people with disabilities in all aspects of research that affect them).

⁹⁵ *The Need for Awareness of Clinical Research*, NAT’L INSTS. OF HEALTH (Mar. 16, 2016), <https://www.nih.gov/health-information/nih-clinical-research-trials-you/need-awareness-clinical-research> [<https://perma.cc/Y6RT-84NW>].

⁹⁶ United Nations, *supra* note 27, at art. 4.

⁹⁷ Douglas Crimp, *Before Occupy: How AIDS Activists Seized Control of the FDA in 1988*, ATLANTIC (Dec. 6, 2011), <https://www.theatlantic.com/health/archive/2011/12/before-occupy-how-aids-activists-seized-control-of-the-fda-in-1988/249302/> [<https://perma.cc/8K5Y-MDPR>]; see Marsha N. Cohen, *Getting New Drugs to People with AIDS: A Public Policy Response to Lansdale*, 18 HASTINGS CONST. L.Q. 471, 481 (1991) (comparing some patients’ access to experimental drugs for treating AIDS to other patients’ access to experimental cancer therapies); Eileen Kelly, *Expanding Prisoners’ Access to AIDS-Related Clinical Trials: An Ethical and Clinical Imperative*, 75 PRISON J. 48, 49 (1995) (arguing that when “the most promising [AIDS] treatments are experimental, community-standard care has come to mean access to experimental drugs” and that “[i]f the goal is to provide to imprisoned people medical care that is comparable to care available in the civilian community . . . then HIV-infected prisoners . . . must have access to clinical drug trials.”).

since ACT UP, clinical trials have become an integral part of healthcare. Writing of the effects of the low participation of African Americans in studies of new cancer drugs, Dr. Kashif Ali, research head at Maryland Oncology Hematology, stated that “minorities, including African Americans, miss out on trials because of financial hurdles, logistical challenges and their lingering distrust of the medical community due to a history of being victimized by medical experimentation.”⁹⁸ In particular:

“They’re potentially losing out on life-extending opportunities because it’s one more option they no longer have,” Ali said. “Especially when patients are in advanced stages of cancer, treatments are like stepping stones: When one stops working, you move on to the next.” Not joining a trial can mean “you’ve lost life expectancy,” he said.⁹⁹

Clinical trials that promise access to otherwise unavailable treatments are often perceived to be of benefit to participants. This is especially true when there are no approved effective treatments.¹⁰⁰ The most significant form of study that may provide a benefit, however, is one that results in access to otherwise unavailable medical care.¹⁰¹

Every federally regulated research study must be approved by an ethics committee that weighs the risks to the individual participants against the expected benefits.¹⁰² The starting point of “risk” is the risk that they already experience. So, for example, a study involving a treatment for persons already diagnosed with a serious illness is evaluated differently than the risk of administering the same treatment to a “healthy volunteer.”¹⁰³ The “benefit”

⁹⁸ Caroline Chen & Riley Wong, *Black Patients Miss Out on Promising Cancer Drugs*, PROPUBLICA (Sept. 19, 2018, 5:00 AM), <https://www.propublica.org/article/black-patients-miss-out-on-promising-cancer-drugs> [<https://perma.cc/PMP8-PN4R>].

⁹⁹ *Id.*

¹⁰⁰ This is the current situation in regard to access to COVID-19 clinical trials but was also the issue in the 1990s regarding access to trials of anti-retroviral. *See* Cohen, *supra* note 97, at 481 (1991) (“Through a mechanism called the ‘compassionate IND,’ the FDA has long allowed experimental drugs to be distributed to patients with no available alternative therapies who were otherwise ineligible for the drug studies.”). Later, strong claims of exclusion were made by prisoners with AIDS. Kelly, *supra* note 97, at 49 (arguing that prisoners must be given access to AIDS-related clinical trials).

¹⁰¹ For other examples of clinical trials involving breakthrough drugs or interventions, see Nancy S. Jecker, Aaron G. Wightman, Abby R. Rosenberg & Douglas S. Diekema, *From Protection to Entitlement: Selecting Research Subjects for Early Phase Clinical Trials Involving Breakthrough Therapies*, 43 J. MED. ETHICS 391, 392–93 (2017).

¹⁰² 45 C.F.R. pt. 46 (2019).

¹⁰³ *See Patient Recruitment: Healthy Volunteers*, CLINICAL CTR. (Apr. 2, 2020), <https://clinicalcenter.nih.gov/recruit/volunteers.html> [<https://perma.cc/BU2U-J4N3>] (“Healthy volunteers have always played a vital role in medical research. When developing a new technique such as a blood test or imaging device, we need clinical research volunteers to help us define the limits of ‘normal.’”).

is also evaluated for each individual. In general, the less risk there is from participating in the study, the less proof there needs to be of benefit.

C. Harm to Society from Excluding People with Disabilities

Another argument against exclusion from a research study is the harm it does to society as a whole by invalidating results.¹⁰⁴ The exclusion of the population of people living with disabilities from research studies diminishes the quality of the information generated by the results of the study being conducted.¹⁰⁵

The second is a much broader category of research of conditions that affect people with and without disabilities, but from which people with disabilities have not been included.¹⁰⁶ For example, a team of obstetricians interested in pregnancy outcomes among women with intellectual and developmental disabilities reported that, “[t]o date, there is no research on the maternal characteristics or pregnancy outcomes of women with [intellectual and developmental disabilities] using a U.S. population-based sample.”¹⁰⁷ Similarly, therapists wanting to compare the effectiveness of different psychological interventions in the population of people with intellectual disabilities found nothing to compare. There were no studies evaluating any interventions with that population.¹⁰⁸

III. LOOKING FOR THE CAUSES OF EXCLUSION

Having documented exclusion and considered its harms, it is important to identify what enables exclusion in order to develop legal strategies to combat it. It is here that another kind of research becomes important: that of scientists who not only document exclusion but seek to find

¹⁰⁴ Feldman et al., *supra* note 46, at 998.

¹⁰⁵ Paul Glasziou, Jan Vandenbroucke & Iain Chalmers, *Assessing the Quality of Research*, 328 *BMJ* 39, 40 (2004); Glenn T. Clark & Roseann Mulligan, *Fifteen Common Mistakes Encountered in Clinical Research*, 55 *J. PROSTHODONTIC RSCH.* 1, 2–4 (2011).

¹⁰⁶ See, e.g., Timothy I. Michaels, Jennifer Purdon, Alexis Collins & Monnica T. Williams, *Inclusion of People of Color in Psychedelic-Assisted Psychotherapy: A Review of the Literature*, *BMC PSYCHIATRY*, July 31, 2018, at 2 (describing exclusion of people of color from testing of psychiatric drugs); Monnica T. Williams, *Psychedelic Psychotherapy is Coming: Who Will Be Included?*, *PSYCH. TODAY* (Aug. 24, 2018), <https://www.psychologytoday.com/us/blog/culturally-speaking/201808/psychedelic-psychotherapy-is-coming-who-will-be-included> [<https://perma.cc/U6QN-RNE9>] (“People of color have not been meaningfully included in this [psychedelic] community.”).

¹⁰⁷ Mitra et al., *supra* note 45, at 300.

¹⁰⁸ Osugo & Cooper, *supra* note 53, at 619–20.

the causal roots of exclusion.¹⁰⁹ Some of the barriers faced by people with disabilities are caused by poverty.¹¹⁰

A. Exclusion at the Starting Gate: Study Designs that Limit Subject Selection

The primary barrier to access to any research studies is the subject selection process.¹¹¹ Whether funded or regulated by law, the choice of who participates is within the discretion of the researcher, just as employers choose their employees and schools choose their students.¹¹² Researchers identify the characteristics of the people they want and then proceed to first recruit and then screen those interested before offering them the opportunity to participate.¹¹³

¹⁰⁹ In particular, the story of the experiences people with disabilities have as research subjects shares many common themes with the story of African Americans. For an excellent overview of these abuses, see CARL H. COLEMAN, JERRY A. MENIKOFF, JESSE A. GOLDNER & EFTHIMIOS PARASIDIS, *THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS* 31–53 (2d ed. 2015). See generally DEPT. OF HEALTH, EDUC. AND WELFARE, NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RSCH., *THE BELMONT REPORT* (1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf [<https://perma.cc/98GD-5CXG>] (memorializing some of the harm that people with disabilities suffered in the United States during the Twentieth Century through their participation in medical research and noting that this harm led to Congress soliciting guidance from ethicists on how to create guidelines to protect vulnerable populations from exploitation).

¹¹⁰ See *supra* note 12 and accompanying text.

¹¹¹ See generally Douglas MacKay, *Fair Subject Selection in Clinical Research: Formal Equality of Opportunity*, 42 J. MED. ETHICS 672 (2016) (identifying issues with the standard method of fair subject selection while proposing potential alternatives).

¹¹² Edward A. Panacek & Cheryl Bagley Thompson, *Sampling Methods: Selecting Your Subjects*, 26 AIR MED. J. 75, 75 (2007) (“The first step in developing a full study protocol is having a clear understanding of the research question to be answered. The next step is to have explicit definitions of the independent and dependent variables of interest in the study. Then the target population can be defined (i.e., who will qualify for the study?). This process involves generation of a list of inclusion and exclusion criteria for potential study subjects.”); see also Elaine Larson, *Exclusion of Certain Groups from Clinical Research*, 26 J. NURSING SCHOLARSHIP 185, 186 (1994) (“Clinical trial investigators have often taken advantage of previously formulated cohorts such as veterans, prisoners, members of the military, physicians, and nurses. Although such cohorts result in skewed samples, they also greatly facilitate study recruitment and follow-up and are cost effective.”); Craig A. Umscheid, David J. Margolis & Craig E. Grossman, *Key Concepts of Clinical Trials: A Narrative Review*, 123 POSTGRADUATE MED. 194, 196 (2011), (“Although RCTs seek to achieve internal validity by enrolling a relatively homogeneous population according to predefined characteristics, narrow inclusion and exclusion criteria may limit their external validity (or ‘generalizability’) to a broader population of patients with highly prevalent comorbidities that may not be included in the sample cohort.”). This theme underscores why an experimental treatment’s “efficacy” (i.e., a measure of the success of an intervention in an artificial setting) may not translate into its “effectiveness” (i.e., a measure of its value applied in the “real world”).

¹¹³ *Financial Assistance for Mesothelioma Patients*, MESOTHELIOMA APPLIED RSCH. FOUND.,

Even if research is recognized as an activity that must include people with disabilities, identifying the actual mechanism for doing so will be important to moving from right to reality. Consistent with the principles of “nothing about us without us,” the first step to addressing the elimination of barriers will be to ask people living with disabilities. Here, again, the urgency of precision medicine’s need for a comprehensive genetic database has put them in the forefront. A recent survey generated by Dr. Maya Sabatello and her team at Columbia seeking information about the attitudes of people with disabilities regarding participation in genetic research serves as a model of what can, and should, be done. The survey they administered over the internet was “based on previous studies on attitudes about genomic research” but in adapting it to the needs of people living with disabilities “[t]hroughout the study, we consulted with experts with disabilities and national organizations of people with disabilities about the survey’s content, format, and programming (e.g., making the survey accessible to screen-readers, i.e., software programs that ‘translate’ text into speech for blind people).”¹¹⁴ The survey’s creators “followed the principles of universal design,¹¹⁵ with the goal of ensuring that the instrument was accessible, easy to understand, and useful to people with a wide range of abilities.”¹¹⁶

B. Exclusion as Protection: Historical Abuse of People with Mental Illness and Developmental Disabilities in the Name Research

People with disabilities have had horrifying experiences as subjects of research.¹¹⁷ At best, they have been treated as disposable and experimented on

<https://www.curemeso.org/mesothelioma-treatment-plan/patient-support-and-resources/financial-assistance-for-mesothelioma-patients/> [https://perma.cc/AM49-QLJ2] (last visited Jan. 24, 2021) (recognizing the cost of traveling to medical centers where trials take place and describing financial assistance the Meso Foundation provides in the form of travel grants); see also Watkins Bruner et al., *supra* note 13, at 708 (suggesting strategies for subjects who have difficulty travelling to drug trial sites).

¹¹⁴ Maya Sabatello, Ying Chen, Yuan Zhang & Paul S. Appelbaum, *Disability Inclusion in Precision Medicine Research: A First National Survey*, 21 GENETICS MED. 2319, 2320 (2019).

¹¹⁵ For an excellent and current analysis of the role of universal design in promoting accessibility, see Ruth Colker, *The Americans with Disabilities Act is Outdated*, 63 DRAKE L. REV. 787, 790 (2015) (“The ideal situation is one in which facilities and services are initially designed in an accessible way. If this were always true, no special rules about modifying facilities or services to create accessibility would be needed.”).

¹¹⁶ Sabatello et al., *supra* note 114, at 2320 (citing ROBERTA NULL, UNIVERSAL DESIGN: PRINCIPLES AND MODELS (2013)).

¹¹⁷ See GEORGE J. ANNAS & MICHAEL A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 268 (1992) (discussing Nazi doctors’ justifications for experimentation, including the belief that certain populations, including “the congenitally handicapped[,] . . . posed a biological threat to . . . the Reich.”); SUZANNE

without their consent.¹¹⁸ At worst, they were subject to torture, including the atrocities experienced by people with disabilities at the hands of doctors and scientists complicit in the Nazi regime of the 1930s and 40s.¹¹⁹ Until very recently, the focus of legal and ethical commentary on people with disabilities as research subjects has been on developing appropriate protections for people with developmental disabilities who may not be able to give fully informed consent¹²⁰ as much as it has been about concern for harm caused by exclusion.¹²¹

One of the most diverse populations within the already diverse community¹²² of people living with disabilities is the group of people whose

E. EVANS, FORGOTTEN CRIMES: THE HOLOCAUST AND PEOPLE WITH DISABILITIES 38 (2004) (“Physicians . . . conduct[ed] so-called scientific experiments on children that allowed them to further their own research agendas. Children with cerebral palsy, Down syndrome, and other neurological conditions were prime subjects for such experiments.”). See generally HUGH GREGORY GALLAGHER, BY TRUST BETRAYED: PATIENTS, PHYSICIANS, AND THE LICENSE TO KILL IN THE THIRD REICH (1990) (describing the murder of disabled victims in Nazi research and euthanasia programs).

¹¹⁸ For accounts of these abuses, see COLEMAN ET AL., *supra* note 109, at 31–53 (describing, among other things, “research scandals” in the United States and the Congressional and regulatory response to them); Yearby, *supra* note 77, at 1223 (proposing an external system to review proposals involving economically disadvantaged minority children as research subjects); *Medical Studies Still Exclude People of Color*, RESEARCH!AMERICA (June 2, 2017), <https://www.researchamerica.org/news-events/medical-studies-still-exclude-people-color> [<https://perma.cc/5K5N-ZVG9>] (“The history of research abuse is alive and well in many of these communities—it lives through word of mouth.”); ADVISORY COMM. ON HUM. RADIATION EXPERIMENTS, FINAL REPORT 3–4, 97–98, 178, 195, 207, 320–21, 330 (1995) (reporting accounts of persons with disabilities exposed to radiation); David Wendler, Raynard Kington, Jennifer Madans, Gretchen Van Wye, Heidi Christ-Schmidt, Laura A. Pratt, Otis W. Brawley, Cary P. Gross & Ezekiel Emanuel, *Are Racial and Ethnic Minorities Less Willing to Participate in Health Research?*, 3 PLOS MED. 201, 208 (2005) (reviewing history of past abuses and concluding that there is insufficient data to substantiate the claim that racial and ethnic minorities are less willing than non-minority individuals to participate in health research).

¹¹⁹ For an informative and frequently updated source of information, see *Nazi Medical Experiments*, U.S. HOLOCAUST MEM’L MUSEUM, <https://www.ushmm.org/wlc/en/article.php?ModuleId=10005168> [<https://perma.cc/63JG-E9A5>] (last visited Jan. 24, 2021).

¹²⁰ In a 1996 JAMA article, Professor Rebecca Dresser noted the absence of specific regulations establishing “standards and procedures for studies involving adults with mental disabilities.” Rebecca Dresser, *Mentally Disabled Research Subjects: The Enduring Policy Issues*, 276 JAMA 67, 67 (1996).

¹²¹ See Lisa Eckstein, *Engaging Racial and Ethnic Groups in the Regulation of Research: Lessons from Research in Emergency Settings*, 12 HOUS. J. HEALTH L. & POL’Y 1, 4 (2011) (discussing historically exploited populations and how research has risked causing harm to those populations).

¹²² Gloria L. Krahn, Deborah Klein Walker & Rosaly Correa-De-Araujo, *Persons with Disabilities as an Unrecognized Health Disparity Population*, 105 AM. J. PUB. HEALTH S198, S198 (2015) (“People with disabilities are a diverse group who share the experience of living with significant limitations in functioning and, as a result, often experience exclusion from full participation in their communities.”).

disabling condition affects their thought processes.¹²³ As a population, they face discrimination, barriers to healthcare, and exclusion from research similar to other people living with disabilities. One of the greatest hurdles to including people with intellectual disabilities in research is the concern that to do so would be unethical because the intellectually disabled may not be competent to give consent and therefore would not be participating voluntarily,¹²⁴ or that they are vulnerable to exploitation and have been exploited by researchers.¹²⁵

The ethical concern about ability to consent translates into the legal principal of competency. Professor Elyn Saks has defined this distinction by referring to legal incompetency as a state of “literal incompetency” in which they have been assigned a “court-appointed guardian” or have themselves transferred decision making authority through a durable power of attorney.¹²⁶ In contrast, she points to the contemporary trend of involving people who may be “developmentally disabled” or “demented” by using “Supported Decision Making” which sets up a “collaborative process.”¹²⁷ It is the latter kind of decision making most relevant to decisions about participation in research because the Common Rule requires that except in very rare circumstances, all potential research subjects participate in the process of decision making, whether they are legally able to give consent or not.¹²⁸ When a potential participant lacks legal capacity, researchers must obtain

¹²³ Because disabilities that affect thought have many different origins, there is no standard vocabulary.

¹²⁴ This is an issue that researchers in Great Britain encountered and overcame. See generally Ruth Northway, Joyce Howard & Lynne Evans, *Participatory Research, People with Intellectual Disabilities and Ethical Approval: Making Reasonable Adjustments to Enable Participation*, 24 J. CLINICAL NURSING 573, 580 (2014) (describing how the authors worked with the ethics review committee to develop materials that would allow research to go forward and recommending to others that “[r]ather than viewing the process as fixed, and systems as precluding the participation of people with intellectual disabilities, potential barriers to participation and to ethical approval were anticipated and strategies put in place to reduce or overcome them.”).

¹²⁵ See Kevin Rak, Alicia K. Matthews, Gabriela Peña, Wendy Choure, Raymond A. Ruiz, Sandra Morales, Amparo Castillo, Jackie Soo & Emily E. Anderson, *Priority Populations Toolkits: Enhancing Researcher Readiness to Work with Priority Populations*, 4 J. CLINICAL & TRANSLAT’L SCI. 28, 28–35 (2019) (including people with disabilities as a priority population and evaluating the efficacy of researchers’ Priority Populations Toolkits).

¹²⁶ Elyn R. Saks, *Competency to Decide for Another*, 30 HEALTH MATRIX: J. L.-MED. 1, 3–4 (2020) [hereinafter Saks, *Decide for Another*] (discussing mechanisms for assessing the competency of substitute decision makers themselves to make decisions about medical care); see also Elyn R. Saks, *Competency to Refuse Medication: Revisiting the Role of Denial of Mental Illness in Capacity Determinations*, 22 S. CAL. REV. L. & SOC. JUST. 167, 167–68 (2013) (discussing the need to respect the decisions of people who deny that they are mentally ill).

¹²⁷ Saks, *Decide for Another*, *supra* note 126, at 4–5.

¹²⁸ 45 C.F.R. § 46.117(c)(1) (2019).

their “assent” to participate rather than “consent.”¹²⁹ As a result, even people who have been found incompetent for some purposes under the laws of their state must be asked for their assent.¹³⁰ Again, this process of collaboration between researchers, participants, and surrogate decision makers is well developed in the U.K., where it is necessary to comply with the mandate of including people who are not legally competent as participants in research.¹³¹ Professor Saks points out that even when an individual “with [a] severe developmental disability who has the mental age of a one-year-old” or “a person in the midst of a psychotic episode with delusions and hallucinations” should “at least” be asked “what he or she wants.”¹³²

They are perceived as adding cost and difficulty to the study as well as possibly invalidating the generalizability of the results.¹³³ None of the FDA’s mandates to diversify the population of people enrolled in clinical trials includes people with disabilities, let alone with any form of mental disability. As a result, they are frequently left out.

This is harmful for all the reasons that exclusion is harmful, but especially so in clinical drug trials because people living with disabilities will be taking drugs that were never tested on them. While the inclusion of people

¹²⁹ *Id.* § 46.402; see also *Informed Consent Tips*, HHS.GOV (March 16, 1993), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html> [<https://perma.cc/5ABA-BWLN>] (listing suggested best practices on how to obtain informed consent from research subjects).

¹³⁰ See, e.g., *Children's Assent*, NAT’L CANCER INST. <https://www.cancer.gov/about-cancer/treatment/clinical-trials/patient-safety/childrens-assent> [<https://perma.cc/CLC7-D9BP>] (last updated March 11, 2020) (describing how to obtain assent, rather than informed consent, from children taking part in clinical trials).

¹³¹ See Shepherd et al., *Protection by Exclusion*, *supra* note 35, at 6 (showing a thorough review of the issues raised, and addressed, in the U.K. regarding participation of people with intellectual disabilities in research); Shepherd et al., *Lacking Capacity*, *supra* note 35, at 8–9 (analyzing the written information given to proxy decision makers for permission to participate in research trials).

¹³² Saks, *Decide for Another*, *supra* note 126, at 6–7; see also *id.* at 8, 10 (proposing her own “gold” standard of competency to make decisions, which requires “(1) ‘understanding,’ in the sense of comprehending what is being told to one; (2) ‘appreciating,’ in the sense of forming acceptable beliefs about what one is told; (3) ‘reasoning’ with the information; and (4) ‘evidencing a choice’” because “[w]ith this standard, ‘understanding’ and ‘appreciating’ require different skills—comprehension and belief-formation”).

¹³³ For a discussion noting both the exclusion of children with intellectual disabilities and possible reasons for this exclusion, see James R. Christensen, Beth S. Slomine, Faye S. Silverstein, Kent Page, Richard Holubkov, J. Michael Dean & Frank W. Moler, *Cardiac Arrest Outcomes in Children With Pre-existing Neurobehavioral Impairment*, 20 PEDIATRIC CRITICAL CARE MED. 510, 516 (2019) (addressing directly the need to include children with intellectual disabilities in research studies and discussing challenges of comparing children with and without pre-existing intellectual disabilities in studying outcomes of children who experienced prolonged comas, but arguing that “this group’s inclusion . . . was both feasible and informative”).

with developmental or intellectual disabilities who cannot, themselves, give consent for research presents similar issues regarding their vulnerability to exploitation, the exclusion of people with diagnosed mental illness is more directly discriminatory and just as illegal. It is also widespread.

In her article titled “Why do clinical trials exclude depressed people?,” journalist Erica Westly addressed the issue in the context of the failure to test Chantix, a drug designed to assist people in quitting smoking, with a population of people who have been diagnosed with depression.¹³⁴ As a result, it was not until after the drug was approved that evidence emerged that it might increase the risk of suicide. She discovered that the exclusion of people with depression from clinical trials was common. She was told that “[a]dherence is often an issue with depressed participants.” In addition to exclusion from smoking trials, Ms. Westly was also told that “excluding participants with depression from weight loss studies amounts to discrimination because it denies them access to potentially helpful treatments.”¹³⁵ Doing her own research into the issue, she found that, “[o]f 38 actively recruiting large-scale late-stage studies known as Phase 3 clinical trials, 21 excluded people with mental illness, and 10 did so for depression specifically.”¹³⁶

Celia Fisher, director of the Center for Ethics Education at Fordham University, has been a longtime advocate for inclusion.¹³⁷ Responding to a question about the reluctance to include people with disabilities in research studies, she stated that “[m]any times, review boards think people with intellectual disabilities should be excluded so we can protect them from coercion or not really understanding the research they’re in.”¹³⁸

However, that protection can cause more harm than good because “treatments for different health problems are not always effective in all populations, so if people with intellectual, or other disabilities, are not included then it violates the principle of justice, because they don’t have the opportunity to benefit from information that can be derived from that research.”¹³⁹ Instead, she advocates that people with intellectual disabilities be included in decision making by developing consent procedures that

¹³⁴ Erica Westly, *Why Do Clinical Trials Exclude Depressed People?*, REUTERS (Mar. 18, 2011, 7:21 AM), <https://www.reuters.com/article/us-trials/why-do-clinical-trials-exclude-depressed-people-idUSTRE72H31320110318> [<https://perma.cc/X6F2-2LHM>].

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Joshua Howgego, *View on Disability: Trials Exclude Vulnerable People*, SCIDEV.NET, (Feb. 14, 2017), <https://www.scidev.net/global/vulnerability/analysis-blog/view-on-disability-trials-exclude-vulnerable-people.html> [<https://perma.cc/JEV6-V8GN>].

¹³⁸ *Id.*

¹³⁹ *Id.*

“involve[] engaging adults with mental disorders as partners in creating respectful and compassionate consent procedures.”¹⁴⁰

Given this history, it is not surprising that they would be reluctant about participating, and perhaps fears of past abuse would deter current researchers.¹⁴¹ Like the reluctance to participate based on past abuse often attributed to African-American rates of participation,¹⁴² people with disabilities, and particularly parents of children with disabilities, have sound reasons to be cautious.¹⁴³

Although exploitation and exclusion may seem to be mutually exclusive, they are, in fact, different sides of the same coin. Both reflected the lived experience of populations which still share the same characteristics that made them vulnerable to exploitation.¹⁴⁴ This is especially true of people

¹⁴⁰ See Celia B. Fisher, *A Goodness-of-Fit Ethic for Informed Consent*, 30 FORDHAM URB. L.J. 159, 171 (2002) (arguing that informed consent policies for adults with mental disorders need to reflect a relational approach in terms of a “goodness-of-fit” between patient characteristics and consent).

¹⁴¹ For arguments on why past abuses should not result in exclusions from research, see Hoffman, *supra* note 83, at 48.

¹⁴² VIVIAN W. PINN, CARL ROTH, ANGELA C. BATES, CARLOS E. CABAN & KIM JAREMA, MONITORING ADHERENCE TO THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH: COMPREHENSIVE REPORT: TRACKING OF HUMAN SUBJECTS RESEARCH AS REPORTED IN FISCAL YEAR 2004 AND FISCAL YEAR 2005, at 78 (2006); Anabella G. Castillo, Lina Jandorf, Linda D. Thélémaque, Sheba King & Katherine Duhamel, *Reported Benefits of Participation in a Research Study*, 37 J. CMTY. HEALTH 59, 60 (2011). See generally Deborah J. Toobert, Lisa A. Strycker, Russell E. Glasgow, Diego Osuna, Alyssa Tinley Doty, Manuel Barrera, Jr., Cristy R. Geno & Debra P. Ritzwoller, *¡Viva Bien!: Overcoming Recruitment Challenges in a Multiple-Risk-Factor Diabetes Trial*, 34 AM. J. HEALTH BEHAV. 432 (2010).

¹⁴³ Eric G. Yan & Kerim M. Munir, *Regulatory and Ethical Principles in Research Involving Children and Individuals with Developmental Disabilities*, 14 ETHICS & BEHAV. 31, 32–33 (2004) (reviewing the history of research involving children with developmental disabilities, including hepatitis vaccine research at Willowbrook State School). Unfortunately, many of the scientists participating in the Willowbrook studies continued to argue that because the children would have been exposed to hepatitis anyway, the benefits to all similarly situated children from the discovery of an effective treatment and then vaccine for Hepatitis B justified experiment. See Saul Krugman, *The Willowbrook Hepatitis Studies Revisited: Ethical Aspects*, 8 REVS. INFECTIOUS DISEASE 157, 161 (1986) (“While I agree with the critics of medical research who state that the ends (successful accomplishments) do not justify the means, I believe that this generalization does not apply to our Willowbrook studies.”).

¹⁴⁴ See Yearby, *supra* note 77, at 1223 (proposing an external system to review proposals involving “economically disadvantaged minority children as research subjects”); *Medical Studies Still Exclude People of Color*, *supra* note 118 (“The history of research abuse is alive and well in many of these communities—it lives through word of mouth.”); Jill A. Fisher & Corey A. Kalbaugh, *Challenging Assumptions About Minority Participation in US Clinical Research*, 101 AM. J. PUB. HEALTH 2217, 2221 (2011) (“Regardless of the reasons for the overrepresentation of minorities in phase I trials and the continued underrepresentation of minorities in phase III trials, we need to consider these phenomena from an ethical standpoint.”).

with intellectual disabilities.¹⁴⁵ But while any proposal for greater inclusion must incorporate an ongoing recognition of their vulnerability and risk of exploitation, the harm of complete exclusion is not justified.¹⁴⁶

C. Addressing Perceptions That People Living with Disabilities Are Not Interested in Research

Some have attributed the failure to include people living with disabilities from research to a belief that, because of the history of past abuse, they do want to be included.¹⁴⁷ Similar claims are made about African Americans: that they choose not to participate because of concern that they will be exploited. As a result, they are not recruited and their absence from research populations is assumed to be a matter of their own choice rather than of their exclusion. The research done recently on the attitudes of people living with disabilities about participating in research is quite similar to the much more extensive information available about African Americans. People living with disabilities are aware of and concerned about past abuse that occurred as part of research studies, but they are not categorically opposed to participating in research.

In the first study ever conducted regarding the interest of people with disabilities in participating in precision medicine research (PMR) that involved taking genetic samples, Dr. Maya Sabatello and her team at Columbia found that “[p]eople with disabilities in our study, across

¹⁴⁵ For an overview of research on abuse of people with disabilities, see CHILD WELFARE INFORMATION GATEWAY, U.S. DEP’T OF HEALTH AND HUMAN SERVS., THE RISK AND PREVENTION OF MALTREATMENT OF CHILDREN WITH DISABILITIES (Jan. 2018), <https://www.childwelfare.gov/pubPDFs/focus.pdf> [<https://perma.cc/TV5J-DLUX>]; *Abuse and Exploitation of People With Developmental Disabilities*, DISABILITY JUST., <http://disabilityjustice.org/justice-denied/abuse-and-exploitation/> [<https://perma.cc/B27M-DP5S>] (last visited Feb. 15, 2021); *Sexual Abuse of People with Disabilities*, RAINN, <https://www.rainn.org/articles/sexual-abuse-people-disabilities> [<https://perma.cc/2KDU-ZGYY>] (last visited Feb. 14, 2021); see also Fisher & Kalbaugh, *supra* note 144, at 2221 (suggesting that discrimination is an explanation for under-represented minorities being over-represented in trials where there is little benefit).

¹⁴⁶ For a history of the development of human subject research regulation in the United States, see Margaret J. Neff, *Informed Consent: What Is It? Who Can Give It? How Do We Improve It?*, 53 RESPIRATORY CARE 1337 (2008).

¹⁴⁷ See 1 WOMEN AND HEALTH RESEARCH: ETHICAL AND LEGAL ISSUES OF INCLUDING WOMEN IN CLINICAL STUDIES 36 (Anna C. Mastroianni, Ruth Faden & Daniel Federman eds., 1994) (“The roots of protectionism go deeper than those of greater access. For example, in the wake of revelations that government-funded research projects engaged in unethical treatment of participants . . . policies were formulated to protect human volunteers. Policies grounded in protectionist considerations contributed to the later exclusion of pregnant women and women of childbearing potential from some clinical studies, most notably, early phase drug trials.”).

racial/ethnic groups, expressed high support for PMR and willingness to participate in a longitudinal study.”¹⁴⁸ But she also found that despite their interest, 76% of the 1294 participants “identified 3 to 8 barriers” to participation.¹⁴⁹ Some of these barriers were directly linked to past abuse. Forty-two percent of respondents endorsed the statement that “PMR might be used to harm people like me.”¹⁵⁰ Other barriers were ones directly related to what they face in accessing any healthcare including “physical obstacles,” “the space and equipment in clinics and health-care facilities are not accessible for me” (56%), and “transportation to health-care facilities is difficult” (53%).¹⁵¹ Large minorities of participants selected: “communication with health professionals is difficult for me” (44%), “information about medical research is not accessible to me” (43%).¹⁵² And the last group reflected concerns about cost such as “transportation to healthcare facilities is too expensive.”¹⁵³

D. Lack of Researchers Who Themselves Live with Disabilities

Another factor identified as posing a barrier to inclusion is the lack of researchers who, themselves, identify as people with disabilities.¹⁵⁴ This is attributable to discrimination at every stage in the education pipeline, but is particularly visible by the time individuals who might be interested in pursuing a scientific career graduate from college. A research study conducted by the National Center for Educational Statistics found that although “relatively equal numbers of students with and without disabilities enter college with the intention to major in a STEM field,” few end up graduating with a STEM degree because of attrition along the way,¹⁵⁵

¹⁴⁸ Sabatello et al., *supra* note 114, at 2324–25.

¹⁴⁹ *Id.* at 2323.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ See Williams, *supra* note 106 (“One factor contributing to low representation is the lack of cultural inclusivity within the research community itself. Historically, psychedelic research has been predominated by White men and there have been few people of color in positions of leadership.”); Natalie Jacewicz, *Why Are Health Studies So White?*, ATLANTIC (June 16, 2016), <https://www.theatlantic.com/health/archive/2016/06/why-are-health-studies-so-white/487046> [https://perma.cc/S4Z2-7SRR] (“The committees that distribute National Institutes of Health dollars, for example, are made up of scientists who have received grants themselves. ‘The scientists that are reviewing the grants are primarily white males,’ said Burchard. ‘They’ll say, ‘This is my friend. He’s white, trying to get blacks, and he can’t do it. Let’s give him a pass.’”).

¹⁵⁵ Rachel Friedensen, *STEM Climate for Students with Disabilities*, AM. COUNCIL ON EDUC.: HIGHER EDUC. TODAY (May 23, 2018), <https://www.higheredtoday.org/2018/05/23/stem->

attributable to a failure to provide appropriate accommodations.¹⁵⁶ In response to this gap, CAST, a nonprofit education research and development organization, recommends that “[o]verall, STEM departments should adopt Universal Design for Learning principles, which will make it easier to address the needs of students with and without disabilities and offer the best possible support to the largest number of students.”¹⁵⁷ These factors are very similar to those recognized as barriers to inclusion of other underrepresented populations in both STEM degrees and STEM research careers.¹⁵⁸ While the NIH is making efforts to address the lack of gender and ethnic diversity among those conducting research, so far there are no similar efforts involving people with disabilities.¹⁵⁹

Although this issue has yet to be researched, another reason for exclusion from research may be directly related to the experiences of people with disabilities in receiving medical care because “77% of patients who participate in a trial learned about it from their health care provider.”¹⁶⁰

E. Exclusion Because of Study Design

The language of the primary statute addressing disability-based discrimination is one of access and inclusion and calls for the removal of

climate-students-disabilities [https://perma.cc/PF36-WD9X] (“[A]bout 25 percent of students in each group have a declared STEM major.”).

¹⁵⁶ See *id.* (“In some instances, instructors can be hostile or indifferent to providing requested accommodations; in others, disability services professionals who help students navigate the accommodations system decide which accommodations would be well-received by instructors, whether or not the students would benefit from them. Additionally, some instructors report that disability services sometimes fail to offer STEM-appropriate accommodations guidance.”).

¹⁵⁷ *Id.* Friedensen references Universal Design for Learning Principles. Those principles can be found on CAST’s website. *About Universal Design for Learning*, CAST, <http://www.cast.org/our-work/about-udl.html> [https://perma.cc/A2JU-8AAR] (last visited Feb. 26, 2021).

¹⁵⁸ Indeed, researchers looking at disparities in research funding for Black applicants attribute the lower rate of funding for Black projects to the fact that “African American scientists may be more likely to pursue research in topic areas such as community-oriented research on disease prevention, for example, versus more microscopic-level research on cellular mechanisms or the basis of genetics. Those population-based topics aren’t being funded as readily.” Emily Vaughn, *What’s Behind the Research Funding Gap for Black Scientists?*, NPR (Oct. 18, 2019, 12:17 PM), <https://www.npr.org/sections/health-shots/2019/10/18/768690216/whats-behind-the-research-funding-gap-for-black-> [https://perma.cc/HSL6-8UYL].

¹⁵⁹ See *Including Women and Minorities in Clinical Research Background*, NAT’L INSTS. HEALTH: OFF. RSCH. ON WOMEN’S HEALTH, <https://orwh.od.nih.gov/womens-health/clinical-research-trials/nih-inclusion-policies/including-women-and-minorities> [https://perma.cc/3BA4-BSGC] (last visited Feb. 26, 2021) (describing policies implemented to better include women and minorities in clinical research).

¹⁶⁰ *The Need for Awareness of Clinical Research*, *supra* note 95.

barriers.¹⁶¹ As a result, the most visible features of the ADA are alterations to physical objects whose original form made them difficult for people with disabilities to use. Things like ramps, elevators, talking street signs, and frustration-free packaging are all associated with addressing disability-based discrimination. However, not all barriers to inclusion are physical.

The primary recommendation of Dr. Rios and other advocates of inclusion is that researchers adopt “universal design” principles which “would provide multiple means of representation, actions, expression and engagement” that would create “physical and social research environments” that are “accessible and appropriate for all children.”¹⁶²

Dr. Rios and her team build on the work of Moore and Williams to “provide[] a conceptual basis for accessible research design” based on already existing recommendations that track the Americans with Disabilities Act’s mandates for preventing discrimination.¹⁶³ Building on a growing body of available research on making both medical care and research studies more accessible to people with disabilities, they suggest “3 levels of implementation: (1) universal design, (2) accommodations, and (3) modifications.”¹⁶⁴

Drawing an analogy to how legal mandates have resulted in the development of guidelines to reduce barriers to full participation in society, Rios highlights guidelines for making research accessible.¹⁶⁵ She ends with a call for action stating that:

Federal funding agencies, such as the NIH and National Institute on Disability, Independent Living, and Rehabilitation Research must emphasize the importance of inclusion of people with disabilities, not only as a civil rights issue but also to enhance the scientific integrity and interpretability of research findings to real-world clinical and policy applications.¹⁶⁶

¹⁶¹ 42 U.S.C. § 12182(b)(2)(A)(iv); *see also* AMERICANS WITH DISABILITIES: PRACTICE AND COMPLIANCE MANUAL § 4:185 (database updated Feb. 2021) (describing the requirements for establishing an architectural barrier claim).

¹⁶² Feldman et al., *supra* note 46, at 1008; *see also* Williams & Moore, *supra* note 36, at 3 (proposing three rules for universal research design: “(i) plan multiple options for people to learn about, respond to, and arrive at opportunities to participate in research . . . (ii) provide multiple means to communicate the information in research instruments and instructions for participants . . . and (iii) provide multiple means of responding to research instruments and self-management interventions”).

¹⁶³ Rios et al., *supra* note 37, at 2138.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.* at 2139.

¹⁶⁶ *Id.* at 2143.

F. Reasons for Exclusion of People with Disabilities Drawn from Exclusion of Other Populations

Some of the barriers that make it difficult for people living with disabilities to participate in research are similar to those of underrepresented populations.¹⁶⁷ For example, a report commissioned by the FDA notes that low income is one of the primary barriers to recruiting a diverse population for research studies because “ethnic minority groups are affected more by poverty and lower socioeconomic status.”¹⁶⁸ These same factors affect people living with disabilities who are also more likely to be low income¹⁶⁹ and thus face financial barriers to participating in studies which require travel.¹⁷⁰

¹⁶⁷ See generally Jennifer Harris & Keri Roberts, *Challenging Barriers to Participation in Qualitative Research: Involving Disabled Refugees*, 2 INT’L J. QUALITATIVE METHODS 14 (2003) (discussing barriers to conducting interviews in qualitative studies with disabled refugees and asylum seekers); Rebecca Luebbert & Amelia Perez, *Barriers to Clinical Research Participation Among African Americans*, 27 J. TRANSCULTURAL NURSING 456 (2016) (discussing the barriers to recruiting African American participants); Ryan D. Nipp, Hang Lee, Elizabeth Powell, Nicole E. Birrer, Emily Poles, Daniel Finkelstein, Karen Winkfield, Sanja Percac-Lima, Bruce Chabner & Beverly Moy, *Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program*, 21 ONCOLOGIST 467 (2016) (discussing financial barriers to participation in cancer trials).

¹⁶⁸ See Isabelle Yates, Jennifer Byrne, Susan Donahue, Linda McCarty & Allison Mathews, *Representation in Clinical Trials: A Review on Reaching Underrepresented Populations in Research*, ASS’N CLINICAL RSCH. PROS. (Aug. 10, 2020), <https://acrpnet.org/2020/08/10/representation-in-clinical-trials-a-review-on-reaching-underrepresented-populations-in-research> [<https://perma.cc/E64Y-MKEG>] (“In a prospective survey study conducted in 2016, patients with household annual incomes below \$50,000 were 27% less likely to participate in clinical trials, and as income dropped, so did the likelihood of trial participation.”); Joseph M. Unger, Julie R. Gralow, Kathy S. Albain, Scott D. Ramsey & Dawn L. Hershman, *Patient Income Level and Cancer Clinical Trial Participation: A Prospective Survey Study*, 2 JAMA ONCOLOGY 137, 137–38 (2016) (“Our research group previously found that patients with annual household incomes below \$50[,]000 were 27% less likely to participate in clinical trials.”).

¹⁶⁹ See *Disability & Socioeconomic Status*, AM. PSYCH. ASS’N, <https://www.apa.org/pi/ses/resources/publications/disability> [<https://perma.cc/6WL7-TAFK>] (last visited Jan. 24, 2021) (“[P]eople with disabilities remain overrepresented among America’s poor and undereducated.”).

¹⁷⁰ OFF. RSCH. ON WOMEN’S HEALTH, NAT’L INSTS. HEALTH, REVIEW OF THE LITERATURE: PRIMARY BARRIERS AND FACILITATORS TO PARTICIPATION IN CLINICAL RESEARCH 1 (n.d.), https://orwh.od.nih.gov/sites/orwh/files/docs/orwh_outreach_toolkit_litreview.pdf [<https://perma.cc/KT4H-4JFW>] (“The most often cited barrier to participation was related to study burden. When a potential participant has no car and buses and taxis are difficult to access or are too costly, the prospect of traveling to a clinical facility for research purposes may present a formidable obstacle.”).

Because access to clinical trials is primarily by physician referral,¹⁷¹ physician bias is also a significant issue in attracting diverse participants.¹⁷²

Other barriers may be specific to their disabling condition such as those that impair the ability to travel.¹⁷³ But there are some forms of discrimination which are particular to people with disabilities, such as assumptions that “their quality of life is poor or that they are unhealthy because of their impairments.”¹⁷⁴ Other assumptions include perceptions that participants will be difficult to communicate with or will have trouble following instructions.¹⁷⁵ Of course, these barriers are exactly the type that federal law requires those bound by the ADA to overcome through reasonable accommodations.

¹⁷¹ See AM. CANCER SOC’Y CANCER ACTION NETWORK, BARRIERS TO PATIENT ENROLLMENT IN THERAPEUTIC CLINICAL TRIALS FOR CANCER: A LANDSCAPE REPORT 24 (2018), <https://www.fightcancer.org/sites/default/files/National%20Documents/Clinical-Trials-Landscape-Report.pdf> [<https://perma.cc/27R9-AUWS>] (“Physicians’ clinical trial referral behavior has not only the ability to affect overall accrual, but it can also affect disparities in accrual. In studies of breast cancer patients, the rate at which women under the age of 65 were offered clinical trials was up to twice that of older women (68% vs 34%) and a similar two-fold referral difference was seen between black and white women.”).

¹⁷² See generally Chloë FitzGerald & Samia Hurst, *Implicit Bias in Healthcare Professionals: A Systematic Review*, BMC MED. ETHICS 1 (2017) (describing physicians’ implicit biases); Sheba George, Nelida Duran & Keith Norris, *A Systematic Review of Barriers and Facilitators to Minority Research Participation Among African Americans, Latinos, Asian Americans, and Pacific Islanders*, 104 AM. J. PUB. HEALTH e16 (2014), (emphasizing the need to recruit diverse populations for research studies).

¹⁷³ See *Common Barriers to Participation Experienced by People with Disabilities*, CTRS. FOR DISEASE CONTROL & PREVENTION: DISABILITY & HEALTH PROMOTION, <https://www.cdc.gov/ncbddd/disabilityandhealth/disability-barriers.html> [<https://perma.cc/8RJ6-TF2Y>] (last updated Sept. 16, 2020) (“Transportation barriers are due to a lack of adequate transportation that interferes with a person’s ability to be independent and to function in society.”). Writing from a personal perspective, Kyle Bryant explains that he makes the effort to participate in a clinical trial despite physical difficulties getting to the hospital where it occurs because “[m]any clinical trials in general fail because of lack of participation. So with numbers like in [his disabling condition], each person has a big responsibility to do their part.” Kyle Bryant, *Why Participate in Clinical Trials?*, HUFFPOST (Dec. 6, 2017), http://www.huffingtonpost.com/kyle-bryant/why-participate-in-clinic_1_b_9712248.html [<https://perma.cc/6S48-G4UC>].

¹⁷⁴ *Common Barriers to Participation Experienced by People with Disabilities*, *supra* note 173.

¹⁷⁵ *Id.* (“Communication barriers are experienced by people who have disabilities that affect hearing, speaking, reading, writing, and or understanding, and who use different ways to communicate than people who do not have these disabilities.”).

G. Justifications for Exclusion

1. Adding cost to the study

Concerns about cost are expressed in study designs intended to achieve useful results as quickly and efficiently as possible by excluding an array of factors that might add to cost or time.

Barring the inclusion of people with disabilities because of the increased resource burden is similar to, and just as illegal as, limiting access to healthcare.

Over the last several years, researchers interested in finding reasons for exclusion have reviewed study designs that excluded people with disabilities to see what modifications would be required and what affect inclusion would have on the study's results.

2. Affecting validity of results

Another aspect of discrimination relevant to people with disabilities is the belief that they are fundamentally different. Just as the Tuskegee Syphilis experiment was based on racist views about differences in physiology, some researchers believe that people with disabilities are different. Dr. Rimmer found that, in examining the criteria for inclusion of the studies they reviewed, "researchers often, if not always, use a 'preexisting condition' or disability as one of [their] exclusion criteria, thus limiting the generalizability of these findings for people with disabilities."¹⁷⁶

Concerns about the ability of people with disabilities to meet the requirements of the study combine factors of cost and physiology. They are expressed by the criteria for inclusion in the study itself.

As early as 2000, Drs. Allan Meyers and Elena Andresen pointed out the need to change the methods researchers were using so as to make them accessible.¹⁷⁷

In looking for reasons why people with disabilities were excluded, Dr. Rios found that many studies have "overly rigid inclusion and exclusion criteria" that screen out people with disabilities without consideration of whether the individual's disabling condition would impact their ability to

¹⁷⁶ Rimmer et al., *supra* note 51, at 2.

¹⁷⁷ See Allan R. Meyers & Elena M. Andresen, *Enabling Our Instruments: Accommodation, Universal Design, and Access to Participation in Research*, 81 ARCHIVES PHYSICAL MED. & REHAB. S5, S8 (2000) ("To our knowledge, no one has filed suit to be included in surveys, but we believe that there are reasonable legal bases for doing so, eg, many surveys are designed and implemented with public money.").

participate.¹⁷⁸ Summarizing these criteria, she wrote that the requirements that resulted in excluding people with disabilities were often “poorly justified.”¹⁷⁹

Like Dr. Rios, though, Dr. Feldman and his research team identified “several modifications that probably would not have invalidated the findings” of the studies they reviewed.¹⁸⁰ Dr. Feldman further rejected arguments against modification by stating that “[t]he possibility of differences in scores based on instruction and test delivery” would not invalidate the findings.¹⁸¹ Instead, he noted that these factors “could be examined in a precursor study or statistically analysed in the same study.”¹⁸²

Dr. Feldman and his research team studied the “justifications for excluding children with disabilities as participants” in the studies they reviewed and found that only “about one-third of the studies explicitly stated and provided a reason” for exclusion.¹⁸³ Reasons for exclusion included: participants being “incapable of meaningful participation, concerns about the validity of psychometric testing, research design concerns, [concerns that participants] would not be able to complete surveys and questionnaires independently, research focuses on normative sampling, and [the desire] to minimise disruptions to the study.”¹⁸⁴

Dr. Feldman concluded that in “the majority of studies that explicitly stated reasons for exclusion,” these reasons were only “justified[] in the absence of possible accommodations.”¹⁸⁵

IV. DEVELOPING A LEGAL RESPONSE TO EXCLUSION: THE AMERICANS WITH DISABILITIES ACT

Having considered the evidence of exclusion of people living with disabilities from research studies, the harm caused by exclusion, and some of

¹⁷⁸ Rios et al., *supra* note 37, at 2138; Feldman et al., *supra* note 46, at 1006.

¹⁷⁹ Rios et al., *supra* note 37, at 2138.

¹⁸⁰ See Feldman et al., *supra* note 46, at 1006 (citation omitted) (giving as examples “simplifying the questions or task; using visuals to help participants understand difficult concepts or procedures; using different presentation modes such as Braille, sign language, communication devices or dictation; accepting alternative modalities for participant responses; providing a scribe for pencil/paper work; and offering frequent breaks.”).

¹⁸¹ *Id.*

¹⁸² *Id.* Using different modalities for collecting research data is a fairly common research challenge with many well-developed solutions. See, e.g., Benjamin Herold, *Comparing Paper-Pencil and Computer Test Scores: 7 Key Research Studies*, EDUC. WK. (Feb. 4, 2016), <https://www.edweek.org/teaching-learning/comparing-paper-pencil-and-computer-test-scores-7-key-research-studies/2016/02> [<https://perma.cc/G8DK-C6P2>] (reviewing techniques, like score adjustments and comparability analysis, for comparing the results of exams taken on paper versus exams taken on a computer).

¹⁸³ Feldman et al., *supra* note 46, at 1002.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* (emphasis omitted).

the possible reasons for exclusion, it is now possible to look directly at how this exclusion can be remedied. This section of the article identifies two primary approaches: 1) applying the anti-discrimination provisions of the Americans with Disabilities Act¹⁸⁶ and 2) incorporating the population of people living with disabilities into existing statutory provisions to diversify the population participating in the most common forms of research conducted in the United States.¹⁸⁷

A. An Overview of Applying Legal Analysis to Disability-Based Discrimination in Research Studies

In order to illustrate how existing provisions of the ADA already prohibit disability-based discrimination, this section takes a functional approach by reviewing the most common settings in which research is conducted and then identifying the significant features that trigger the protection of existing laws prohibiting disability-based discrimination. It starts with the most common settings—research studies conducted and funded by the federal government—and then considers the more complex, more varied scenarios of biomedical research involving the development of drugs, vaccines, and devices. In so doing, it makes no attempt to offer a comprehensive overview of the ADA or disability law.¹⁸⁸ Instead, this article is intended to inspire action and awareness, not suggest litigation strategies to lawyers already expert in protecting the rights of people living with disabilities either as individuals or collectively as a class.¹⁸⁹

¹⁸⁶ For an overview of the purposes of the ADA, see 29 U.S.C. §§ 701–796.

¹⁸⁷ The ADA does not extend outside the territorial limitations of the United States. Research conducted or funded by the federal government is subject to U.S. human subject protection law so if inclusion mandates were incorporated into that law, they would apply overseas. Nor has Congress required research pursuant to an application for permission from the FDA to market a new drug be conducted according to U.S. law. Jennifer S. Bard, *A Taxonomy for Analyzing Legal and Ethical Issues Arising When Conducting Human Subject Research Outside the Borders of One's Own Country*, 37 HOUS. J. INT'L L. 1, 41 (2015). For a review of the regulation of overseas research see *id.*

¹⁸⁸ There are certainly extensive resources doing just that. See Derek Warden, *Methods of Administration*, 10 HOUS. L. REV. 39, 46, 66 (2020) (describing the ADA generally and advocating for use of the “methods of administration” claim); see also Colker, *supra* note 115, at 788 (discussing the ADA and its failure to respond to technological advances as needed); cf. Claire Raj, *The Promise and Peril of Using Disability Law as a Tool for School Reform*, 94 WASH. L. REV. 1831, 1833–38 (2019) (discussing the use of class actions under Title II to extend the provisions of special education services to a population of children who, by virtue of growing up in a specific community, have been exposed to Adverse Childhood Experiences (ACEs) that impair their ability to learn).

¹⁸⁹ For a history of the creation of Protection and Advocacy organizations (P&As) from the government's perspective, see Statement of Interest of the United States at 2–5, Disability

However, both for those familiar with the ADA but not the process by which research is conducted and those comfortable with the mechanisms of research but not with the provisions of the ADA, it will create a framework for working together to promote inclusion and harness available legal protections against disability-based discrimination. Where needed, it will identify some gaps in the ADA that will need to be addressed through litigation or legislation. It concludes that the existing provisions of the ADA as currently interpreted by the federal courts already provide a strong schema for promoting inclusion of people living with disabilities in most of the settings where research is conducted in the United States.

B. Legal Protection Against Disability-Based Discrimination

Discrimination based on disability is prohibited in the United States by an interlocking network of federal and state laws¹⁹⁰ similar to those prohibiting discrimination based on race, religion, sex, or national origin.¹⁹¹

Rights N.Y. v. N. Colonie Bd. of Educ., 2016 WL 1122055 (N.D.N.Y. 2016) (No. 1:14-cv-774 (DNH/RFT)). For a history of advocacy organizations from a parent's perspective, see Melanie Perkins McLaughlin, *Parent? Advocate? Or Both?: What Happens When We Put the Burden on Parents to Push and Fight for Their Children With Special Needs?*, HARV. ED., Summer 2018, at 25, <https://www.gse.harvard.edu/sites/default/files/edmag/pdfs/2018-sum-20.pdf> [<https://perma.cc/2NP8-2PXS>]. See generally *Protection and Advocacy for People with Disabilities*, NAT'L DISABILITY RTS. NETWORK, <https://www.ndrn.org/> [<https://perma.cc/6NPD-JKJ4>] (last visited Jan. 22, 2021) (describing how P&As and Client Assistance Programs (CAPs) are "the nation's largest providers of legal advocacy services for people with disabilities.").

¹⁹⁰ All states must, at a minimum, comply with all the provisions of the ADA but are free to add expanded protection. Many states have used their authority to extend the definition of a qualified plaintiff beyond that of the ADA and deliberately extended protection to people statutorily excluded. For a discussion of the relationship between state and federal laws prohibiting disability-based discrimination, see Sara Wilson, *State-Level Activism in the Disability Context: Ensuring Protections for People with Disabilities Through American Federalism and the Fourteenth Amendment Equal Protection Clause*, 15 J. HEALTH & BIOMEDICAL L. 173, 183–84 (2019). For an overview of state laws prohibiting disability-based discrimination, see STEPHEN A. ROSENBAUM, DISABILITY RIGHTS AND PUBLIC ACCOMMODATIONS: STATE-BY-STATE 6–26 (2011) http://www.adasoutheast.org/publications/ada/public_accommodations_disability_rights_state-by-state_Final.pdf [<https://perma.cc/H836-P4LA>]. For a discussion of the distinct Titles of the ADA, see U.S. Dep't of Justice, *A Guide to Disability Rights Law*, BRAINLINE, <https://www.brainline.org/article/guide-disability-rights-laws> (last visited June 17, 2020) [<https://perma.cc/L6GB-H44U>].

¹⁹¹ SARAH PARKER HARRIS, ROBERT GOULD, GLENN FUJURA, ROBIN JONES, PATRICK OJOK & AVERY OLMSTEAD, DEP'T OF DISABILITY & HUMAN DEV., SYSTEMATIC REVIEW PROJECT YEAR 1: SCOPING REVIEW OF THE ADA 3 (2013), https://adata.org/sites/adata.org/files/files/ADAKT_ScopingReview_TechnicalReport_2013.pdf [<https://perma.cc/YEN4-ZPAA>] ("The Americans with Disabilities Act (ADA) is the cornerstone of US civil rights policy for people with disabilities, and the primary legislative tool for ensuring their full and equal treatment

Unlike the laws prohibiting other forms of discrimination, however, the ADA imposes a positive obligation to promote “inclusion” of people with disabilities.¹⁹² As Professor Jasmine Harris explains, “[p]rescriptively, Congress designed the [ADA] to ensure that people with disabilities are not denied access to employment, public services, and places of public accommodations.”¹⁹³ What can make disability discrimination law challenging to apply is that within that general proscription against discrimination, Congress has distinguished between the obligations of public entities (federal, state, and city governments) and those of private entities.¹⁹⁴ As a result, every case of disability-based discrimination must begin by characterizing the status of the entity accused of discrimination and then identifying the limits to which that particular covered entity must make changes.¹⁹⁵ While there are differences in the language of Title II and III, as Professor Laura Rothstein explains, “[s]ubstantively, the two statutes provide for both nondiscrimination and reasonable accommodations and require that ‘reasonable’ efforts must be in place to ensure access.”¹⁹⁶ Both Titles excuse entities from making “unduly burdensome” accommodations that

as citizens. The legislative intent of the ADA is to protect against discrimination while simultaneously fostering social inclusion across all domains of public life.”). *See generally* Kimani Paul-Emile, *Blackness as Disability*, 106 GEO. L.J. 293, 321 (2018) (“Persons with disabilities have faced discrimination much like that experienced by black people.”).

¹⁹² In *Olmstead v. L.C. ex rel. Zimring*, Justice Ginsburg, writing for the Supreme Court, upheld the Justice Department’s interpretation of the ADA as requiring “community-based treatment for persons with mental disabilities when the State’s treatment professionals determine that such placement is appropriate . . . and the placement can be reasonably accommodated, taking into account the resources available to the State.” 527 U.S. 581, 607 (1999). *See also* Paul-Emile, *supra* note 191, at 327 n.211 (citing Mary C. Cerreto, *Olmstead: The Brown v. Board of Education for Disability Rights—Promises, Limits, and Issues*, 3 LOY. J. PUB. INT. L. 47 (2001); Don Schanche, Jr., *Georgia Lags in Responding to Olmstead Decision*, MACON TEL., Mar. 30, 2003, at A10 (“The *Olmstead* Decision has become as significant for people with disabilities as ‘*Brown v. Board of Education*’ was for the civil rights movement.”)).

¹⁹³ Jasmine E. Harris, *The Aesthetics of Disability*, 119 COLUM. L. REV. 895, 896 (2019).

¹⁹⁴ Nicole Flynn, *Public and Private University Accessibility Law*, CIELO24 (Jan. 6, 2016), <https://cielo24.com/2016/01/public-and-private-university-accessibility-law/> [<https://perma.cc/P4CA-CSAU>] (explaining differences in how ADA accessibility requirements are applied in public and private universities); *The Tale of Two Titles: Title II and Title III; ADA Compliance*, BRAILLE WORKS (Apr. 19, 2016, 11:10 AM), <https://brailleworks.com/title-ii-and-title-iii-ada-compliance/> [<https://perma.cc/ZX8Y-QXVW>].

¹⁹⁵ *Frequently Asked Questions About Titles II and III of the ADA*, U.S. DEP’T JUST., <https://www.justice.gov/crt/frequently-asked-questions-about-titles-ii-and-iii-ada> [<https://perma.cc/T2TG-KN8W>] (“If a criterion screens out or tends to screen out individuals with disabilities, it may only be used if necessary for the provision of the services.”).

¹⁹⁶ Laura Rothstein, *Forty Years of Disability Policy in Legal Education and the Legal Profession: What Has Changed and What Are the New Issues?*, 22 AM. U. J. GENDER, SOC. POL’Y & L. 519, 528 (2014).

“fundamentally alter the nature of the program”¹⁹⁷ or are “necessary for the provision of services.”¹⁹⁸ But Title II holds public entities to a higher standard of proving that an accommodation which does not alter the nature of a program or is not necessary to the provision of the services is nevertheless unduly burdensome because it is “either financially or administratively” unreasonable.¹⁹⁹ Because the standards of proof under Title II and Title III are different, the analysis of remedies for disability discrimination will depend on first characterizing the entity conducting the research as either public or private.²⁰⁰ Then, if private, remedies depend on whether or not in conducting research it is serving as a place of public accommodation.

The current structure of federal laws prohibiting disability-based discrimination represent a legislative process that began in 1968 with the Fair Housing Act and took its current form with the passage of Section 504 of the Rehabilitation Act of 1973 (Section 504), which prohibits disability-based discrimination by “any program or activity” receiving federal financial assistance.²⁰¹ Today, the Rehabilitation Act has been joined by the four titles of the Americans with Disabilities Act.²⁰² Taken together, they are intended to combat the “various forms of discrimination” that “individuals with disabilities continually encounter.”²⁰³ The four titles of the ADA provide similar, although not identical, protections against disability discrimination and also vary in terms of available remedies.²⁰⁴ Additional protection is

¹⁹⁷ *Id.*

¹⁹⁸ *Frequently Asked Questions About Titles II and III of the ADA*, *supra* note 195.

¹⁹⁹ Rothstein, *supra* note 196, at 528.

²⁰⁰ Donald J. Spero, *Burdens of Proof of Reasonableness and Undue Harship Under Titles I, II and III of the Americans With Disabilities Act*, FLA. MEDIATION GRP. (Sept. 19, 2014, 11:33 AM), http://www.2mediate.com/articles/spero/2002_Burdens_of_Proof_of_Reasonableness_and_Undue_Hardship_Americans_With_Disabilities_Act.html [https://perma.cc/UQ9S-D6CS].

²⁰¹ 29 U.S.C. § 794(a) (“No otherwise qualified individual with a disability in the United States . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency . . .”).

²⁰² For an overview of disability discrimination created by the office that enforces the ADA, see *Discrimination on the Basis of Disability*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> [https://perma.cc/GYN9-J4EQ] (last visited Jan. 23, 2021).

²⁰³ See 42 U.S.C. § 12101(a)(5) (outlining examples of these various forms of discrimination, “including outright intentional exclusion, the discriminatory effects of architectural, transportation, and communication barriers, overprotective rules and policies, failure to make modifications to existing facilities and practices, exclusionary qualification standards and criteria, segregation, and relegation to lesser services, programs, activities, benefits, jobs, or other opportunities”).

²⁰⁴ See Ruth Colker, *ADA Title III: A Fragile Compromise*, 21 BERKELEY J. EMP. & LAB. L. 377, 377–78 (2000) (“[T]he broad coverage of ADA Title III came at a price—as part of a

provided by federal laws that protect against discrimination based on genetics.²⁰⁵

The ADA was passed in an atmosphere of great hope. Its stated purpose is to “to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities.”²⁰⁶ President George H.W. Bush said at the ADA signing ceremony, “[w]ith today's signing of the landmark Americans with Disabilities Act, every man, woman, and child with a disability can now pass through once-closed doors into a bright new era of equality, independence, and freedom.”²⁰⁷

The Justice Department, which enforces ADA violations, has been steadfast in its position that there should be no disability-based discrimination in health care. Settling a case with a physician who refused to treat a patient with HIV, the Justice Department announced: “Discrimination by those in the medical profession breaks a trust critical to ensuring access to appropriate treatment for all.”²⁰⁸ This prohibition applies not just to all publicly run or funded entities or institutions but extends to any entity providing healthcare to the public. Title III directly identifies as covered entities the “professional office of a health care provider, hospital, or other service establishment,” whether it is public or not.²⁰⁹

‘fragile compromise.’ In return for a broad list of covered entities, civil rights advocates agreed to a limited set of remedies under ADA Title III. When private parties bring suit under ADA Title III, they are only able to obtain injunctive relief and are *not* able to obtain monetary damages.” (internal citation omitted)). For an overview of the challenges of enforcing the ADA because of the difference in available remedies see Harris, *supra* note 12, at 481 (“Yet the ADA’s remedial structure in many ways creates “rights without remedies” with respect to public entities by denying plaintiffs monetary damages. Weak enforcement of Title II and the lack of a threat of damages beyond cases of “intentional discrimination,” coupled with Title III’s sole remedy of injunctive relief, continue to limit the ADA’s deterrent value and promise of integration.” (internal citations omitted)).

²⁰⁵ While beyond the scope of this article, the Genetic Information Nondiscrimination Act of 2008 extended some of the ADA’s protection to people who are discriminated against based on genetic information. For a comparison of the protections of the ADA and GINA, see Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 J.L. MED. ETHICS 837 (2008).

²⁰⁶ 42 U.S.C. § 12101(b)(1).

²⁰⁷ Remarks on Signing the Americans with Disabilities Act of 1990, 1990 PUB. PAPERS 1065 (July 26, 1990).

²⁰⁸ Press Release, U.S. Dep’t. of Just., Justice Department Settles with Indiana Doctor Over Discrimination Against an Individual with HIV, No. 16-419 (Apr. 7, 2016).

²⁰⁹ 42 U.S.C. § 12181(7)(F); 28 C.F.R. § 36 app. C, at 952 (2019) (explaining that the office of a health care provider may qualify as a covered entity even if it is located in a private home); see also Elizabeth Pendo, *Disability, Equipment Barriers, and Women's Health: Using the ADA to Provide Meaningful Access*, 2 ST. LOUIS U. J. HEALTH L. & POL’Y 15, 33 (2008) (“Title III of the ADA prohibits discrimination in privately-owned places of public accommodation, and provides that ‘[n]o individual shall be discriminated against on the basis

But well beyond healthcare, the ADA's prohibition against disability-based discrimination reaches into all aspects of daily life prohibiting discrimination in housing, education, healthcare, and transportation.²¹⁰ It prohibits discriminatory behavior by public and private entities and imposes affirmative obligations to create an accessible environment.²¹¹

C. Making a Prima Facie Case for Discrimination Under the ADA

All the statutes discussed in this article providing protection from disability-based discrimination require potential plaintiffs to first prove that they meet the legal criteria for bringing suit. Relief under Title II of the ADA requires that a plaintiff prove that she is a qualified person with a disability²¹² and under Title III that she is a person with a disability.²¹³ Many state laws

of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.' 'Public accommodation' includes a wide range of commercial facilities and establishments, and explicitly includes the private offices of health care providers and private hospitals." (footnotes omitted)).

²¹⁰ See Laura F. Rothstein, *Teaching Disability Law*, 48 J. LEGAL EDUC. 297, 299 (1998) ("The ADA . . . greatly extended coverage of the private sector, prohibiting discrimination by most private employers, by most private programs of public accommodation, and by state and local governmental entities (including those not receiving federal funds)." citations omitted)).

²¹¹ *Id.*

²¹² *Bragdon v. Abbott*, 524 U.S. 624, 632 (1998). Because the definition of a qualified plaintiff, disabling conditions, and major life activities were expanded by the ADA Amendments Act of 2008, 42 U.S.C. § 12102(2)(A), it is important that only cases after that date are used as precedents on this issue. It is also important to note that while the standards for inclusion are not meant to be definitive, there are very specific standards for exclusion. See 29 U.S.C. § 705(20)(F) ("'[I]ndividual with a disability' does not include an individual on the basis of—(i) transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders; (ii) compulsive gambling, kleptomania, or pyromania; or (iii) psychoactive substance use disorders resulting from current illegal use of drugs."); 42 U.S.C. § 12211(b) (mirroring the exclusions listed under 29 U.S.C. § 705(20)(F)). For an overview of how plaintiffs qualify under all provisions of the ADA, see ADA Amendments Act of 2008 (ADAAA), Pub. L. No. 110-325, § 2(b)(1), 122 Stat. 3553, 3554 (2008) (codified at 42 U.S.C. § 12102).

²¹³ 42 U.S.C. § 12133; 28 C.F.R. § 36.104 (2019); see also U.S. Dep't of Just., *ADA Title III Technical Assistance Manual: Covering Public Accommodations and Commercial Facilities*, ADA.GOV, <https://www.ada.gov/taman3.html> [<https://perma.cc/24LY-UV6>] (last visited Jan. 24, 2021) ("Title III protects three categories of individuals with disabilities: 1) Individuals who have a physical or mental impairment that substantially limits one or more major life activities; 2) Individuals who have a record of a physical or mental impairment that substantially limited one or more of the individual's major life activities; and 3) Individuals who are regarded as having such an impairment, whether they have the impairment or not.").

prohibiting disability discrimination expand the definition of disability, thereby widening the population of plaintiffs in those jurisdictions who can seek protection.²¹⁴ This analysis assumes a plaintiff who meets the threshold status requirement of the legal provision under which they are bringing action.

D. Proving Discrimination

Having proved that the plaintiff is qualified, and the entity covered, the next task is proving that they have experienced discrimination. They do not have to prove that the discrimination was deliberate or even that discrimination was of a type against which Congress intended to protect.²¹⁵ Title II's provisions related to actions of the federal government, are intended not only to "protect disabled persons from discrimination arising out of . . . discriminatory animus," but also to protect from "thoughtlessness," "indifference," or "benign neglect."²¹⁶ Moreover, Title II of the ADA provides that "[a] public entity, in providing any aid, benefit, or service, may not . . . utilize criteria or methods of administration . . . [t]hat have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability."²¹⁷

A study that explicitly excludes people living with a disability from participation would be a paradigmatic example of active discrimination. But it is also possible to prove discrimination without evidence of an explicit ban. Title II of the ADA prohibits public entities from "utiliz[ing] criteria or methods of administration"²¹⁸ that "deny individuals with disabilities access to the public entity's services, programs, and activities."²¹⁹ This so called "methods of administration" provision extends broad protection for practices of an entity that serve to discriminate or which have a disparate impact on participation.

²¹⁴ See Eve Hill & Sheila Khan-Variba, *Challenging Barriers*, L.A. LAW., Nov. 2005, at 31 (reviewing California's statutes prohibiting discrimination on the basis of disability); 42 U.S.C. § 12102(2) (providing federal definition of disability and related terms); 28 C.F.R. § 36.105 (2019) (same).

²¹⁵ See *Bostock v. Clayton Cty.*, 140 S.Ct. 1731, 1751 (2020) (citing *Pa. Dep't of Corrs. v. Yeskey*, 524 U.S. 206, 212 (1998)) (noting that in the presence of "unambiguous statutory text" prohibiting discrimination, "whether a specific application was anticipated by Congress 'is irrelevant'").

²¹⁶ *Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996) (quoting *Alexander v. Choate*, 469 U.S. 287, 295 (1985)).

²¹⁷ 28 C.F.R. § 35.130(b)(1)–(3) (2019).

²¹⁸ *Id.* § 35.130(b)(3).

²¹⁹ *Id.* § 35 app. B, at 709.

In broad terms, this means proof that a covered entity²²⁰ has treated them differently from the way it treats people who are not living with a disability. Unless the plaintiff seeks to recover money damages, she does not have to prove that the discrimination was intentional, just that it was a result of the covered entity's actions. But if the plaintiff proves intentional discrimination, the burden shifts to the defendant.

There are three major legal theories available to a qualified plaintiff for proving discrimination.²²¹ They are that a covered entity's actions were intentional disparate treatment,²²² they had a disparate impact on the plaintiff because of her disability,²²³ or the covered entity failed to provide reasonable

²²⁰ The obligations of a covered entity are broad. As the Office of Civil Rights explains:

Covered entities must not, on the basis of disability:

- Exclude a person with a disability from a program or activity;
- Deny a person with a disability the benefits of a program or activity;
- Afford a person with a disability an opportunity to participate in or benefit from a benefit or service that is not equal to what is afforded others;
- Provide a benefit or service to a person with a disability that is not as effective as what is provided others;
- Provide different or separate benefits or services to a person with a disability unless necessary to provide benefits or services that are as effective as what is provided others;
- Apply eligibility criteria that tend to screen out persons with disabilities unless necessary for the provision of the service, program or activity.

Covered entities must:

- Provide services and programs in the most integrated setting appropriate to the needs of the qualified individual with a disability;
- Ensure that programs, services, activities, and facilities are accessible;
- Make reasonable modifications in their policies, practices, and procedures to avoid discrimination on the basis of disability, unless it would result in a fundamental alteration of the program;
- Provide auxiliary aids to persons with disabilities, at no additional cost, where necessary to afford an equal opportunity to participate in or benefit from a program or activity

Discrimination on the Basis of Disability, *supra* note 202.

²²¹ See *Davis v. Shah*, 821 F.3d 231, 259 (2d Cir. 2016) (quoting *Fulton v. Goord*, 591 F.3d 37, 43 (2d Cir. 2009)) (“To state a prima facie claim under either provision, a plaintiff must establish ‘(1) that she is a qualified individual with a disability; (2) that she was excluded from participation in a public entity's services, programs or activities or was otherwise discriminated against by a public entity; and (3) that such exclusion or discrimination was due to her disability.’”).

²²² See, e.g., *Sch. Bd. Of Nassau Cnty. v. Arline*, 480 U.S. 273, 283 n.9 (1987) (noting Representative Vanik's view that the Rehabilitation Act prohibits exclusion of a child with cerebral palsy from the classroom of a public school because the child “produced a nauseating effect” on his peers).

²²³ See, e.g., *Prewitt v. U.S. Postal Serv.*, 662 F.2d 292, 306 (5th Cir. Unit A Nov. 1981) (“In

accommodation.²²⁴ All three could be the basis for a claim based on exclusion from research. Courts have consistently found that plaintiffs need not prove individual animus or “obviously exclusionary conduct.”²²⁵ Instead, discrimination can be proved by deliberate indifference.²²⁶

1. Disparate treatment: deliberate discrimination

Under the ADA, the term “disparate treatment”—common to many federal anti-discrimination laws—means treatment based on deliberate discrimination rather than an accidental phenomena outside the entity’s control which it had no duty to prevent.²²⁷ In *Prewitt v. U.S. Postal Service*, the U.S. Court of Appeals for the Fifth Circuit identified actions taken based on “social bias” regarding persons with disabilities as “intentional discrimination” which resulted in treating people with disabilities differently from people in similar circumstances without disabilities.²²⁸ At this stage of establishing a prima facie case, it is the treatment that matters, not the reason for it. So, for example, if a study design does not explicitly exclude people with disabilities but is designed in a way that prevents them from participating, such as requiring the ability to hold a pencil or stand for a chest x-ray,²²⁹ plaintiffs can argue that otherwise neutral provisions can have a disparate impact on people with disabilities because it prevents them from participating.²³⁰ Both Title II and Title III mandate that covered entities must affirmatively identify barriers to accessibility and take steps “as may be necessary to ensure that no individual with a disability is excluded, denied

the discriminatory impact context . . . [a]ll a plaintiff need prove to establish a prima facie case is that the challenged standard disparately disadvantages the protected group of which he is a member . . .”).

²²⁴ 42 U.S.C. § 12112(b)(5); *see also, e.g., Prewitt*, 662 F.2d at 305 (finding that plaintiff may be entitled to relief if the postal service refused to hire him “even though he could have performed the essentials of the job if afforded reasonable accommodation”); *Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996) (finding that the state’s animal quarantine law that disproportionately affected people with disabilities violated the ADA).

²²⁵ *See Chapman v. Pier 1 Imps.*, 631 F.3d 939, 945 (9th Cir. 2011) (“The concept of ‘discrimination’ under the ADA does not extend only to obviously exclusionary conduct—such as a sign stating that persons with disabilities are unwelcome or an obstacle course leading to a store’s entrance.”).

²²⁶ *Alexander v. Choate*, 469 U.S. 287, 295 (1985) (“Discrimination against the handicapped was perceived by Congress to be most often the product, not of invidious animus, but rather of thoughtlessness and indifference—of benign neglect.”).

²²⁷ 42 U.S.C. § 12112.

²²⁸ *Prewitt*, 662 F.2d at 305 n.19.

²²⁹ For examples of these kinds of exclusionary designs, *see Rios et al., supra* note 37.

²³⁰ *See, e.g., Crowder v. Kitagawa*, 81 F.3d 1480, 1484 (9th Cir. 1996) (finding that a six-month quarantine of all dogs had a disparate impact on individuals with disabilities who needed access to their service animals)

services, segregated or otherwise treated differently than other individuals because of the absence of *auxiliary aids and services*.”²³¹

If a plaintiff proves discrimination, then the burden shifts to the entity to show why they should not make the changes necessary to change whatever is causing the discrimination.²³²

2. Justifying inaccessible research

Finally, if a qualified plaintiff can prove disability-based discrimination by a covered entity, the final issue is the entity’s legal obligation to make research accessible.²³³ Both Title II and III require covered entities to make reasonable efforts.²³⁴ The ADA identifies three major actions which covered entities must do in order to make reasonable accommodations that assure access for people with disabilities. They are the “modifications to rules, policies, or practices;”²³⁵ “the removal of . . . barrier[s];”²³⁶ and the provision of “auxiliary aids and services.”²³⁷ It is, therefore, likely that most research will take place in an entity that is either covered by Title II because of how it is funded or Title III because it provides healthcare. The extent of changes that entities conducting research have to make in order to include people with disabilities is defined differently under Title II and Title III. A Title II covered entity must make “reasonable modifications” that would accommodate the plaintiff’s disability unless

²³¹ 42 U.S.C. § 12182(b)(2)(A)(iii) (emphasis added).

²³² See Warden, *supra* note 188, at 53 (arguing for greater use of the methods of administration clause as a stand-alone cause of action to “address animus, deliberate indifference, thoughtlessness, apathy, and even benign neglect” if the result is disability-based discrimination).

²³³ See generally Rios et al., *supra* note 37 (outlining their approach to making research accessible modeled on universal design, accommodations, and modifications).

²³⁴ See Rothstein, *supra* note 196, at 528 (“Substantively, the two statutes provide for both nondiscrimination and reasonable accommodations and require that ‘reasonable’ efforts must be in place to ensure access. Accommodations that are unduly burdensome, either financially or administratively, or that fundamentally alter the nature of the program, are not required.”).

²³⁵ 42 U.S.C. § 12131(2) (“The term ‘qualified individual with a disability’ means an individual with a disability who, with or without reasonable modifications . . . meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity.”).

²³⁶ 42 U.S.C. § 12182(b)(2)(A)(v); see AMERICANS WITH DISABILITIES: PRACTICE AND COMPLIANCE MANUAL, § 4:106 (database updated Feb. 2021) (“The obligation to engage in readily achievable barrier removal under Title III . . . is a continuing one, and it is discriminatory for a public accommodation to fail to take reasonable measures to remove architectural and other barriers to accessibility.”); *id.* § 1:264 (“[A] plaintiff’s failure to expressly ‘request’ an accommodation is not fatal to a claim where the defendant otherwise had knowledge of an individual’s disability and needs but took no action.”).

²³⁷ 28 C.F.R. § 35.160(b)(1) (2019); see *id.* § 36.303(b)(1)–(4) (defining auxiliary aids and services under Title III).

doing so would “‘fundamentally alter’ the services or accommodations being offered.”²³⁸ A Title III covered entity must also make “reasonable modifications” that would accommodate plaintiff’s disability, but only if “such removal is ‘readily achievable’” without fundamentally altering public accommodation’s nature.²³⁹

Looking ahead, plaintiffs seeking these accommodations are likely to find that their most significant barrier is the existence of rigid exclusion criteria that arbitrarily exclude people with disabilities without proper consideration of whether the disability would actually impact participation.²⁴⁰

E. How do Research Sites or Sponsors Qualify as “Covered Entities”?

Once a plaintiff is found to be eligible to invoke the ADA’s protection, the next issue is whether she can meet her burden of proving that she has experienced discrimination by a covered entity. Below is a brief explanation of proving discrimination under the ADA, followed by scenarios, each of which matches provisions of the ADA applicable to the entity most likely to conduct related research studies.

1. Research conducted by the federal government: a vaccine trial at NIH

The Federal Government conducts research studies directly through a network of entities connected with different agencies and entities.²⁴¹

Research conducted by a public entity such as a government agency or a public school, university, or hospital is subject to Section 504 of the Rehabilitation Act and Title II²⁴² of the Americans with Disabilities Act.²⁴³

²³⁸ See *Spector v. Norwegian Cruise Line Ltd.*, 545 U.S. 119, 128–29, 135–36 (2005) (holding that foreign cruise ships in U.S. waters were subject to Title III of the ADA, mandating that specific accommodations sought by the plaintiffs be made because they were “readily achievable,” did not pose “a significant risk to health or safety of others,” and were “easily accomplishable and able to be carried out without much difficulty or expense.”).

²³⁹ *Id.* at 126–27.

²⁴⁰ For examples of these kinds of exclusionary designs see Rios et al., *supra* note 37, at 2138.

²⁴¹ *Finding a Clinical Trial*, NAT’L INSTS. HEALTH (Nov. 6, 2018), <https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinical-trial> [<https://perma.cc/5D5U-7X4D>].

²⁴² Title II prohibits any public entity from discriminating against “qualified” persons with disabilities in the provision or operation of public services, programs, or activities. 42 U.S.C. §§ 12131–12134.

²⁴³ *Warden*, *supra* note 188, at 46 (citing *Windham v. Harris Cty.*, 875 F.3d 229, 235 (5th Cir. 2017)) (“Generally, in order to win any case under this provision, plaintiffs must prove a prima facie case: (1) that he or she is an otherwise qualified individual with a disability (2) that they have been subject to discrimination by a public entity and (3) that such discrimination was by reason of disability.”).

Section 504 provides that “no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.”²⁴⁴ This is true whether the study involves the federal government directly, as the hundreds of clinical trials conducted by the NIH in its facilities in Bethesda, Maryland,²⁴⁵ or by a state chartered public university, academic medical center, or hospital.²⁴⁶ The Act defines the term “public entity” to include state and local governments, as well as their agencies and instrumentalities.²⁴⁷

2. Research funded by the federal government

While the amount of research conducted directly by the federal government is fairly small, the amount of research funded by the federal government is vast.²⁴⁸ These studies extend across a broad array of fields

²⁴⁴ 42 U.S.C. § 12132.

²⁴⁵ *Finding a Clinical Trial*, *supra* note 241 (“The NIH maintains an online database of clinical research studies taking place at its Clinical Center, which is located on the NIH campus in Bethesda, Maryland.”).

²⁴⁶ For an overview of the structure of higher education in the United States see U.S. Dep’t of State, *Understanding U.S. Higher Education*, EDUC. USA, <https://educationusa.state.gov/foreign-institutions-and-governments/understanding-us-higher-education> [<https://perma.cc/DC6R-3F3C>] (last visited Feb. 27, 2021). In the United States a “public university” refers to an institution of higher education chartered directly by the federal, state, or city government. See Gary Moss, *What Does it Mean to be a Public University?*, U.N.C. CHAPEL HILL: AROUND CAMPUS (Apr. 18, 2018) <https://www.unc.edu/posts/2018/04/18/mean-public-university/> [<https://perma.cc/H4ZB-NPWC>]. The first public university in the United States was chartered by the State of North Carolina in 1789 with legislation stating that “it is the indispensable duty of every Legislature to consult the happiness of a rising generation and endeavor to fit them for an honourable discharge of the social duties of life, by paying the strictest attention to their education.” *Id.*

²⁴⁷ 42 U.S.C. § 12131(1).

²⁴⁸ For example, the National Science Foundation, “funds research and education in most fields of science and engineering. It does this through grants, and cooperative agreements to more than 2,000 colleges, universities, K-12 school systems, businesses, informal science organizations and other research organizations throughout the United States.” *About Funding*, NAT’L SCI. FOUND., <https://www.nsf.gov/funding/aboutfunding.jsp> [<https://perma.cc/M3UF-BBY4>] (last visited Feb. 27, 2021); see also *NSF By Account*, NAT’L SCI. FOUND., <https://dellweb.bfa.nsf.gov/NSFFundingbyAccountConstantDollars.pdf> [<https://perma.cc/9KFJ-KCM7>] (last visited Jan. 23, 2021) (stating that for Fiscal Year 2020, the National Science Foundation was allocated federal funding of \$8,278,330,000); *Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NAT’L INSTS. HEALTH: REPORT (Feb. 24, 2020), <https://report.nih.gov/funding/categorical-spending> [<https://perma.cc/5HZ7-QCFQ>] (outlining funding amounts allocated to research studies by condition or disease category); *Budget*, NAT’L INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do/budget> [<https://perma.cc/F8PX-9NWV>] (last visited Feb. 27, 2021) (“NIH invests about \$41.7 billion annually in medical research for the American people.”).

ranging from education²⁴⁹ to social science to medicine.²⁵⁰ It would be difficult to construct an argument exempting research funded by the federal government from federal laws preventing disability discrimination. By prohibiting disability-based discrimination by any program or activity receiving Federal financial assistance, Title II of the Americans with Disabilities Act applies to anything a public entity does.²⁵¹

3. Exclusion from a clinical trial not directly funded by the federal government

Therefore, even research sponsored by a private entity which does not provide health care to the public must comply with the ADA if it occurs as part of the care a patient is receiving.²⁵²

While different entities use different definitions, this article will use the term “clinical trials” to encompass all biomedical research that involves an intervention which must be conducted under the supervision of a licensed physician.²⁵³ A biomedical research study that takes place in an entity,

²⁴⁹ For an example of a research study involving humans but not clinical medicine, see *For Worriers, Expressive Writing Cools Brain on Stressful Tasks*, MSU TODAY (Sept. 14, 2017), <http://msutoday.msu.edu/news/2017/for-worriers-expressive-writing-cools-brain-on-stressful-tasks/> [https://perma.cc/P76F-64KN].

²⁵⁰ See CLINICALTRIALS.GOV [https://perma.cc/4PPM-9LGK] (last visited Jan. 23, 2021) (“ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.”).

²⁵¹ 42 U.S.C. § 12131(1) (extending protections of Rehabilitation Act to all public entities); 28 C.F.R. § 35, app. B (2019) (providing guidance on Title II application to matters within the scope of the Department of Transportation).

²⁵² Raymond T. Foster, Sr., *Academic Medical Centers, Private Industry, and Clinical Trials: How Do We Achieve Fairness, Objectivity, and Balance?*, 18 INT’L UROGYNECOLOGY J. 233, 235 (2007) (“With shrinking public money to support clinical research, we will have increased reliance on private sponsorship in the future. Our challenge is to establish a system of checks and balances that protects the welfare of our patients, allows us to continue to conduct quality research, and rewards private companies that make products that improve the health of our patients.”).

²⁵³ As defined by the National Institutes of Health, “[c]linical research is medical research involving people.” “Clinical trials” are “research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective.” *What Are Clinical Trials and Studies?*, NAT’L INST. ON AGING, <https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies> [https://perma.cc/8S79-CBRK] (last visited Jan. 23, 2021). The FDA’s definition is somewhat different, “[c]linical trials are voluntary human research studies designed to answer specific questions about the safety and effectiveness of drugs, vaccines, devices, and other therapies—or to study new ways of using existing treatments.” *FDA Encourages More Participation, Diversity in Clinical Trials*, FDA (Jan. 16, 2018), <https://www.fda.gov/consumers/consumer-updates/fda-encourages-more-participation-diversity-clinical-trials> [https://perma.cc/G5E3-KRJE].

whether public or private, which provides health care to the public must make “services fully available to individuals with disabilities.”²⁵⁴ There are four overlapping federal laws that directly prohibit disability-based discrimination by individuals and entities which provide healthcare. The first three, Section 504 of the Rehabilitation Act and Sections II and III of the ADA, apply to the entity as a whole, not specifically to the delivery of healthcare. The fourth, Section 1557 of the Affordable Care Act, is specific to the provision of healthcare. Because there has not, as yet, been a reported case applying any of these provisions to exclusion from a research study, the scenarios below match typical research settings to the most plausible relevant legal provisions with the understanding that more than one can apply depending on a future court’s characterization of the activity or entity involved.

One of the most interesting issues that will arise in seeking inclusion in a clinical trial is the fluid legal boundary between “health care” and “research” when both are being provided by publicly funded entities.

Almost all colleges, universities, and academic medical centers in the United States, whether public or private, receive some federal funding which, in turn, requires them to follow federal law.²⁵⁵ These studies would most likely be clinical trials intended to gather information needed to seek FDA approval to market a new drug, device, or biologic.²⁵⁶ The paradigm examples are the vaccine trials currently being conducted by companies like Moderna that are unaffiliated with any universities or academic medical centers and which involve healthy individuals who are not seeking or receiving healthcare.

²⁵⁴ U.S. DEP’T OF JUST. & U.S. DEP’T OF HEALTH & HUM. SERVS., ACCESS TO MEDICAL CARE FOR INDIVIDUALS WITH MOBILITY DISABILITIES 1 (2010), <https://www.hhs.gov/sites/default/files/ocr/civilrights/understanding/disability/adamobilityimpairmentsguidance.pdf> [<https://perma.cc/WN6B-T788>].

²⁵⁵ See Dean Clancy, *A List of Colleges That Don’t Take Federal Money*, DEAN CLANCY (Aug. 10, 2020), <https://deanclancy.com/a-list-of-colleges-that-dont-take-federal-money> [<https://perma.cc/U572-VKZK>] (listing eighteen “colleges in the United States [that], in order to preserve their liberty and independence, do not accept grants from the federal government or participate in any federal financial-aid or student-loan program”); Ibbby Caputo & Jon Marcus, *The Controversial Reason Some Religious Colleges Forgo Federal Funding*, ATLANTIC (July 7, 2016) <https://www.theatlantic.com/education/archive/2016/07/the-controversial-reason-some-religious-colleges-forgo-federal-funding/490253> [<https://perma.cc/Z2HM-DGN9>] (“Thirty-eight religiously affiliated institutions have received exemptions from Title IX, according to a list released by the Education Department.”); Lydia Wheeler, *DeVos: All Schools That Receive Federal Funds Must Follow Federal Law*, THE HILL (June 6, 2017, 11:07 AM) <https://thehill.com/regulation/administration/336517-devos-all-school-that-receive-federal-funds-must-follow-federal-law> [<https://perma.cc/NQ93-7SGP>] (reporting Secretary DeVos’ answer to questions from Senator Patty Murray about the requirement that schools receiving federal funding follow federal law).

²⁵⁶ It is difficult to find any official list of colleges that do not take federal funding, although the general agreement is that it is very small.

In guidance directed specifically to physicians, the Justice Department wrote that: “The ADA requires access to medical care services and the facilities where the services are provided. Private hospitals or medical offices are covered by Title III of the ADA as places of public accommodation.”²⁵⁷ Public hospitals must make their “services available through alternative methods Under Title II, a public entity must ensure that its program as a whole is accessible.”²⁵⁸

A hospital, clinic, or doctor’s office, even if privately owned, is a place of public accommodation.²⁵⁹ A person who is “subject[] to discrimination” or “who has reasonable grounds for believing that such person is about to be subjected to discrimination” on the basis of disability may bring a private right of action to seek injunctive relief under Title III.²⁶⁰ Certainly these organizations are bound by the provisions of Title I of the ADA, which prohibits discrimination in employment. There is nothing about a pharmaceutical company or a biomedical research organization operating in the United States that would permit them to discriminate based on disability in the studies they conduct.

Both the type of discrimination and the nature of the entity charged with discrimination determine which Title of the ADA to apply. The activities that make up “research” and nature of the entities where research is conducted make the Rehabilitation Act, Title II²⁶¹, and Title III the most likely sources of protection.

4. Research conducted by or at a private entity which receives federal funding: the case of Dolly Parton

Another scenario where an individual might seek admission to a clinical trial is one where a privately funded study is conducted at an institution which receives federal funding.²⁶²

A recent news item revealing that the Dolly Parton Foundation had contributed \$1,000,000 to COVID-19 research conducted at Vanderbilt

²⁵⁷ ACCESS TO MEDICAL CARE, *supra* note 254, at 1.

²⁵⁸ *Id.*

²⁵⁹ 28 C.F.R. § 36.104 (2019).

²⁶⁰ 28 C.F.R. § 36.501(a) (2019). Title III of the ADA, which, among other things, requires an entity operating “public accommodations” to make “reasonable modifications” in its policies “when . . . necessary to afford such . . . accommodations to individuals with disabilities, unless the entity can demonstrate that making such modifications would fundamentally alter the nature of such . . . accommodations,” 42 U.S.C. § 12182(b)(2)(A)(ii).

²⁶¹ 42 U.S.C. §§ 12131–34.

²⁶² “No otherwise qualified individual with a disability . . . shall, solely by reason of his or her disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 29 U.S.C. § 794(a).

University illustrates the growing role of private foundations in funding biomedical research.²⁶³ But for purposes of the ADA, the relevant factor is the place where the research is conducted, not the funding source. Nor is it relevant that the hospital or university, here Vanderbilt, is private.²⁶⁴ Title III of the ADA prohibits disability-based discrimination by private, commercial entities which meet the criteria for designation as places of “public accommodation” or the legal criteria for being so considered.²⁶⁵ This includes private hospitals, universities, and research institutes.²⁶⁶

All universities that receives federal research funding and all medical facilities that provides healthcare to the public will still be covered entities under the ADA, regardless of who funds the research.

5. Exclusion from biomedical research in a place that does not receive federal funding but does provide health care to the public

If the medical facility is public, then it comes under the jurisdiction of the Rehab Act and Title II.²⁶⁷ This includes doctors’ offices located in private homes.²⁶⁸ Title III of the ADA defines “[h]ospitals, clinics, and

²⁶³ Dave Paulson, *Dolly Parton Says She’ll Donate \$1 Million for Coronavirus Research at Vanderbilt*, TENNESSEAN (Apr. 1, 2020, 11:53 AM), <https://www.tennessean.com/story/entertainment/music/2020/04/01/dolly-parton-donating-1-million-coronavirus-research-vanderbilt/5104191002/> [https://perma.cc/G9M5-YHJ8]; Maria Cramer, *Dolly Parton: Singer, Songwriter, Pandemic Savior?*, N.Y. TIMES (Nov. 17, 2020), <https://www.nytimes.com/2020/11/17/arts/music/dolly-parton-moderna-virus.html> [https://perma.cc/HPD5-5VQX]; Allie Clouse, *Dolly Parton Helped Fund 95% Effective Moderna COVID-19 Vaccine That Could End Pandemic*, TENNESSEAN (Nov. 17, 2020, 2:47 PM), <https://www.tennessean.com/story/entertainment/2020/11/17/dolly-parton-vaccine-funding-moderna-covid-19/6322836002> [https://perma.cc/PG4M-324G].

²⁶⁴ Title III provides that “[n]o individual shall be discriminated against on the basis of a disability in the full and equal enjoyment of the . . . privileges . . . of any place of public accommodation.” 42 U.S.C. § 12182(a). See *Tennessee v. Lane*, 541 U.S. 509, 516–17 (2004) (describing the functions of Titles I, II, and III of the ADA).

²⁶⁵ Title III uses the word “accommodation” in two different ways. The first, “[p]ublic accommodations,” is a description of the characteristics of a private entity that nevertheless must offer the same kind of access to people living with disabilities as a public entity. Private entities which offer public accommodations may not “discriminate[] on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation.” 42 U.S.C. § 12182(a).

²⁶⁶ *Id.* § 12181.

²⁶⁷ *Id.* §§ 12131–12134.

²⁶⁸ *Id.* § 12181(7)(F); 28 C.F.R. § 36 app., at 696 (2019) (providing that the office of a health care provider may be included even if it is located in a private home, to the extent it is a portion of the home); see also Pendo, *supra* note 209, at 33 (“Title III of the ADA prohibits discrimination in privately-owned places of public accommodation, and provides that ‘[n]o individual shall be discriminated against on the basis of disability in the full and equal

doctors' offices" as places of "public accommodation" because they provide healthcare services to the public.²⁶⁹ If a private entity meets the criteria for being designated a public entity, then it must provide the accommodations to give people with disabilities the same access as people without disabilities.²⁷⁰

F. Obligations to Eliminate Barriers to Access under Title III of the ADA

1. Biomedical research studies conducted by private entities who do not provide healthcare

The scenarios above primarily concerned research studies that were covered under Title II as public²⁷¹ or Title III as places of public accommodation, including providers of health care to the public,²⁷² but there are some studies that take place in private facilities that are either in-house to the drug developer or stand-alone Clinical Research Centers.²⁷³ The issue with these entities is whether they would be classified as places of public accommodation. In order to sell a newly developed drug in the United States, a drug company ("the Sponsor") must obtain the approval of the Food and Drug Administration ("FDA") which is charged by Congress to certify that

enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation.' 'Public accommodation' includes a wide range of commercial facilities and establishments, and explicitly includes the private offices of health care providers and private hospitals." (footnotes omitted)).

²⁶⁹ 28 C.F.R. § 36.505 (2019).

²⁷⁰ *Baughman v. Walt Disney World Co.*, 685 F.3d 1131, 1135 (9th Cir. 2012) ("Public accommodations must start by considering how their facilities are used by non-disabled guests and then take reasonable steps to provide disabled guests with a like experience.").

²⁷¹ *See Manhattan Cmty. Access Corp. v. Halleck*, 139 S. Ct. 1921, 1932 (2019) ("[B]eing regulated by the State does not make one a state actor."). Nor are private universities state actors simply because they are subject to state regulation. *See Klunder v. Brown Univ.*, 778 F.3d 24, 33 (2015) (citing *Krohn v. Harvard L. Sch.*, 552 F.2d 21, 24 (1st Cir. 1977) ("[T]he receipt of state financial assistance, the regulation by a public accreditation council, and the authority of that council to oversee disciplinary procedures 'were insufficient attributes of government involvement to render the university's disciplinary proceedings 'state action' for section 1983 purposes")).

²⁷² There is a dispute in the Circuits about how far to extend the definition of "place." *Compare, e.g., Magee v. Coca-Cola Refreshments USA, Inc.*, 833 F.3d 530, 534, 534 n.23 (5th Cir. 2016) (holding that a Coca-Cola machine is not a "place" of public accommodation), *with, e.g., Morgan v. Joint Admin. Bd.*, 268 F.3d 456, 459 (7th Cir. 2001) (holding that "public accommodation" under Title III was not limited to a "physical site" and therefore could extend to the terms of a retirement plan).

²⁷³ For a description of the purposes of a phase one trial, see Amit Mahipal & Danny Nguyen, *Risks and Benefits of Phase 1 Clinical Trial Participation*, 21 *CANCER CONTROL* 193 (2014).

drugs for sale in the United States have gone through a testing process to ascertain that they are safe²⁷⁴ and effective.²⁷⁵

To reach this determination, the FDA “doesn't actually test drugs itself” but rather relies on information provided by the Sponsor.²⁷⁶ Their goal is to “ensure . . . that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks.”²⁷⁷ The Sponsor cannot begin drug testing in the United States until it receives preliminary clearance from the FDA and receives approval for an Investigational New Drug (“IND”). An IND obligates the Sponsor to put its study under the supervision of an Institutional Review Board (“IRB”).²⁷⁸ The Government itself often uses the word “oversight” to describe the FDA’s role in the Clinical Trials conducted by Sponsors.²⁷⁹ Recent legislation streamlining the FDA drug review process could be used to support an argument that clinical drug trials

²⁷⁴ Farrah R. Raja, *Evidentiary Standards for Drug Approvals in the 21st Century Cures Act: A Continued Trend Towards Valuing Access over Safety for Pharmaceutical Drugs*, 18 N.C. J.L. & TECH. 409, 415 n.40 (2017) (“Reasonable safety is demonstrated when, based on scientific evidence, the probable benefits from using the drug for its intended use outweigh the probable risks associated with using the drug.” (citing Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-17, 52 Stat. 1040 (1938))).

²⁷⁵ “Substantial evidence of effectiveness” is shown when qualified experts have reviewed data from adequate and well-controlled studies and can conclude from the results of the data that the drug will have its intended effect for its prescription and labeling uses. *Id.* at 414 (quoting Michelle Meadows, Promoting Safe and Effective Drugs for 100 Years, U.S. FOOD & DRUG ADMIN. (Jan.–Feb. 2006), <https://www.fda.gov/files/Promoting-Safe-and-Effective-Drugs-for-100-Years-%28download%29.pdf> [<https://perma.cc/WMM5-267P>]); see also *Development and Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> [perma.cc/9ZRW-ELCE] (last updated Oct. 28, 2019) (explaining the FDA’s role as being one “[e]valuat[ing] new drugs before they can be sold” to “not only prevent[] quackery, but also provide[] . . . doctors and patients the information they need to use medicines wisely.”).

²⁷⁶ *Development and Approval Process (Drugs)*, *supra* note 275.

²⁷⁷ *Id.*

²⁷⁸ See *Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm> [<https://perma.cc/9MLT-HDVG>] (last updated Sept. 5, 2018) (“Advertising for recruitment into investigational drug, biologic or device studies should not use terms such as ‘new treatment,’ ‘new medication’ or ‘new drug’ without explaining that the test article is investigational. A phrase such as ‘receive new treatments’ leads study subjects to believe they will be receiving newly improved products of proven worth.”)

²⁷⁹ In response to criticism from the Office of the Inspector General about gaps in the FDA’s oversight, see OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., THE FOOD AND DRUG ADMINISTRATION’S OVERSIGHT OF CLINICAL TRIALS (2007), <https://oig.hhs.gov/oei/reports/oei-01-06-00160.pdf> [<https://perma.cc/4JG4-RETK>]. As of September 16, 2016, all clinical trials must be registered with the FDA. *Submit Studies to ClinicalTrials.gov PRS*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/manage-recs/submit-study> [<https://perma.cc/PX8P-SWPY>] (last visited June 17, 2020).

are activities sponsored by the federal government.²⁸⁰ The FDA itself reports annually on its role in bringing to market “novel” or “breakthrough drugs.”²⁸¹

Commonly, the first stage of drug trials involving human participants is conducted with healthy people who are administered the products under study and then monitored for adverse results.²⁸² Facilities running stage one trials do not provide medical care, nor do they receive federal funding. They maintain no relationship with treating physicians who are affiliated with covered entities, but instead, they advertise directly to the public for participants in the initial stages of drug testing.

There has been little litigation clarifying the status of stand-alone or private clinical drug trial facilities relevant to the ADA. They have been found subject to federal regulation regarding protection of human participants in research and have been carefully described by the federal regulations applying HIPAA privacy provisions. But whether or not any of these factors or the “involvement” of the federal government makes a Clinical Drug Trial an “activity” of the federal government is as yet unresolved.

In the absence of any legal resolution of the issue, sponsors may look to a case from the Tenth Circuit rejecting a claim that a plasma donation center, also a federally regulated entity, must be made accessible because it was a place of public accommodation.²⁸³ Instead, the Tenth Circuit held that the plasma center was a “service establishment”²⁸⁴ though its purpose was not to serve individuals who wanted to donate the plasma that the company then sold to hospitals.²⁸⁵ Rather, its obligation was to be accessible to its plasma customers, hospitals, and blood banks.²⁸⁶ In the same way, a Clinical Trial Center may be seen as a “service establishment” to those using the clinical data, not those providing it.

²⁸⁰ 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified as amended in scattered sections of 21, 34, 38, and 42 U.S.C.).

²⁸¹ *Novel Drugs Summary 2015*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm> [<https://perma.cc/DTZ4-N9TK>] (last updated Jan. 12, 2016) (“[N]ovel drugs [] are among the more truly innovative products that often help advance clinical care to another level.”) CDER issues annual reports on the approval of novel drugs.

²⁸² Some people make a living by participating in phase one trials. Cf. GPGP.NET – CLINICAL TRIALS, MEDICAL TRIALS, UK, CANADA, USA, <http://www.gpgp.net/> [<https://perma.cc/9E7U-8Q57>] (last visited June 17, 2020) (providing a directory of trials seeking participants).

²⁸³ *Levorsen v. Octapharma Plasma, Inc.*, 828 F.3d 1227, 1234–35 (10th Cir. 2016).

²⁸⁴ 42 U.S.C. § 12181(7)(F).

²⁸⁵ *Levorsen*, 828 F.3d at 1234–35.

²⁸⁶ *Id.*

2. Making reasonable accommodations under Title III of the ADA

Title III of the ADA requires that public entities take “reasonable” measures to remove access barriers.²⁸⁷ The party refusing to make the accommodation bears the burden of proving that it is not reasonable.²⁸⁸ To do so, it must show either that the accommodation “would result in an undue financial or administrative burden” or would affect “a fundamental alteration in the nature of the service.”²⁸⁹ Each of these categories has been subject to significant legal interpretation.

3. Obligation of entities subject to Title III to eliminate barriers to access to a research study

One of the likely objections to providing accommodations to make research studies accessible is that doing so might invalidate research results.²⁹⁰ Since neither Title II nor Title III impose an absolute duty on a covered entity to provide a qualified plaintiff an accommodation for the purposes of preventing discrimination, this objection will need to be faced and rebutted.

²⁸⁷ 42 U.S.C. § 12131(2).

²⁸⁸ 28 C.F.R. § 35.150(a)(3) (2019). The regulations state that:

[I]n determining whether an action would result in an undue burden, factors to be considered include—

- (1) The nature and cost of the action needed under this part;
- (2) The overall financial resources of the site or sites involved in the action; the number of persons employed at the site; the effect on expenses and resources; legitimate safety requirements that are necessary for safe operation, including crime prevention measures; or the impact otherwise of the action upon the operation of the site;
- (3) The geographic separateness, and the administrative or fiscal relationship of the site or sites in question to any parent corporation or entity;
- (4) If applicable, the overall financial resources of any parent corporation or entity; the overall size of the parent corporation or entity with respect to the number of its employees; the number, type, and location of its facilities; and
- (5) If applicable, the type of operation or operations of any parent corporation or entity, including the composition, structure, and functions of the workforce of the parent corporation.

Id. § 36.104.

²⁸⁹ *Id.* § 35.150(a)(3); *see also id.* § 35.164 (relieving public entities from making an accommodation that “would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens.”); *Prewitt v. U.S. Postal Serv.*, 662 F.2d 292, 300 (5th Cir. 1981) (discussing that a program’s eligibility requirement may discriminate against the disabled if the program’s purposes may not be achieved without the requirement).

²⁹⁰ *See supra* notes 180–89 and accompanying text.

Title III requires that private entities offering public accommodations must be proactive in their removal of barriers. Whether or not there is a specific individual seeking access, their programs, equipment, and facilities must be “designed, constructed, and altered in compliance with the accessibility standards established by this part.”²⁹¹ Because of this obligation of accessibility regardless of need, Courts have been receptive to arguments by covered entities seeking to limit their obligations. In 2001, the Supreme Court in *PGA Tour v. Martin* held that it would be illegal discrimination to enforce a rule prohibiting players from travelling between holes by cart against an individual with a qualified disability that made it unreasonably difficult for him to walk the course.²⁹² The Court’s caveat was that the PGA could enforce the rule if they could demonstrate that doing so “would fundamentally alter the nature of [the golf tournament].”²⁹³

Quoting Title III, the Court found that by not waiving the rule to allow travel by cart the PGA was failing “to make reasonable modifications in policies, practices, or procedures, when such modifications are necessary to afford [access] to individuals with disabilities.”²⁹⁴ Looking at another Title III case four years later, the Court further explained that Title III “requires only ‘reasonable modifications’ that would not fundamentally alter the nature of the service provided.”²⁹⁵ An entity also may have eligibility requirements that “impose legitimate safety requirements that are necessary for safe operation.”²⁹⁶ However, those “safety requirements must be based on actual risks and not on mere speculation, stereotypes or generalizations about people with disabilities.”²⁹⁷ A private entity providing a public accommodation must therefore present objective evidence that the inclusion of a person with a disability in its activity would “fundamentally alter” its character.²⁹⁸ In *Bragdon v. Abbott*, Justice Ginsburg concurred with the majority opinion, but wrote to note that in order to legally refuse to treat a patient with HIV in his office a Dentist would have to prove that doing so “posed ‘a significant risk to [his] health or safety of that [could not] be eliminated by a modification of policies, practices, or procedures’”²⁹⁹

²⁹¹ 28 C.F.R. § 36.101(a) (2019).

²⁹² *PGA Tour, Inc. v. Martin*, 532 U.S. 661, 688–89 (2001).

²⁹³ *Id.* at 682 (citing 42 U.S.C. § 12182(b)(2)(A)(ii)).

²⁹⁴ *Id.*

²⁹⁵ *Tennessee v. Lane*, 541 U.S. 509, 532 (2004).

²⁹⁶ 28 C.F.R. § 36.301(b) (2019).

²⁹⁷ *Id.*

²⁹⁸ See *Bragdon v. Abbott*, 524 U.S. 624, 649 (1998) (“The existence, or nonexistence, of a significant risk must be determined from the standpoint of the person who refuses the treatment or accommodation, and the risk assessment must be based on medical or other objective evidence.”).

²⁹⁹ *Id.* at 656.

4. Provision of auxiliary aids and services

Next to ramps and elevators, the most familiar accommodations are resources that provide assistance communicating.³⁰⁰ These include but are not limited to³⁰¹ “Braille materials, qualified interpreters, assistive listening devices, open or closed captioning and hearing aid compatible telephones.”³⁰² Both Title II³⁰³ and Title III mandate that covered entities must affirmatively identify barriers to accessibility and take steps “as may be necessary” to provide “auxiliary aids and services.”³⁰⁴ Dr. Rios argues that these kinds of auxiliary aids “[k]eep the construct or essential elements consistent, while eliminating difficulties associated with functional deficits.”³⁰⁵ Describing their work in designing accessible data collection devices, one research team noted, “People with disabilities have often been excluded from participation in clinical trials and other health-related research, either intentionally because they did not meet the inclusion criteria, or unintentionally because they were not able to travel to the research site or because no accommodations were available for responding to paper-and-pencil test questionnaires.”³⁰⁶

³⁰⁰ See, e.g., *Auxiliary Aids and Service*, NAT’L DISABILITY NAVIGATOR RES. COLLABORATIVE, <https://nationaldisabilitynavigator.org/ndnrc-materials/disability-guide/auxiliary-aids-and-services/> [<https://perma.cc/HQ3B-8Q9B>] (last visited July 17, 2020) (describing devices or services that enable effective communication).

³⁰¹ See 28 C.F.R. Pt. 35, app. A, at 560 (2019) (“The Department recognized in the preamble to the 1991 title II regulation that the list of auxiliary aids was ‘not an all-inclusive or exhaustive catalogue of possible or available auxiliary aids or services. It is not possible to provide an exhaustive list, and an attempt to do so would omit the new devices that will become available with emerging technology.’ The Department continues to endorse that view; thus, the inclusion of a list of examples of possible auxiliary aids in the definition of “auxiliary aids” should not be read as a mandate for a title II entity to offer every possible auxiliary aid listed in the definition in every situation.” (citation omitted)).

³⁰² See *id.* § 35.160(b)(2) (requiring public entities to provide “the type of auxiliary aid and service necessary to ensure effective communication.”); *id.* § 36.303(b) (defining the types of auxiliary aids and services under Title III).

³⁰³ See 42 U.S.C. § 12182 (prohibiting discrimination based on disability and including that “failure to take such steps as may be necessary” to ensure no one is excluded based on the “absence of auxiliary aids and services” unless such steps would result in “undue burden” is prohibited).

³⁰⁴ *Id.*

³⁰⁵ See Rios et al., *supra* note 37, at 2139 (providing, as an example, allowing a person with “limited hand control” to dictate responses to a survey rather than write them).

³⁰⁶ Mark Harniss, Dagmar Amtmann, Debbie Cook & Kurt Johnson, *Considerations for Developing Interfaces for Collecting Patient-Reported Outcomes that Allow the Inclusion Of Individuals with Disabilities*, 45 MED. CARE S48, S48–54 (2014).

Since many research studies both recruit on the web³⁰⁷ and rely on participants having access to their websites, they are likely to be already under statutory obligation to make their websites accessible.³⁰⁸ Websites themselves have been found to be places of “public accommodation” under Title III.³⁰⁹

5. Is exclusion of people with disabilities a necessary action which would otherwise fundamentally alter the character of the research?

Anticipating the objections that researchers would raise in the face of demands that they include people with disabilities, Rios and her team considered objections based on the risk of harm to the scientific validity of the study.³¹⁰ For this concern to justify exclusion, however, researchers would have to show that the modifications required for exclusion would fundamentally alter the activity or create genuine safety risks. One accommodation might be to allow a service animal to access many places where a pet could not go, but without allowing the animal to access an operating room or even an x-ray suite where it might harm itself or others.³¹¹

Arguments against including people with disabilities take many forms but one of the most common is that their inclusion would impair the generalizability of the collected data. Moore and her team have suggested that using the same statistical methods that allow researchers to break out results

³⁰⁷ The National Institute of Health provides a website as a resource for patients and families, as do many universities. See CLINICALTRIALS.GOV, <https://clinicaltrials.gov/> [<https://perma.cc/4PPM-9LGK>] (last visited June 17, 2020) (providing NIH resources on research studies and clinical trials); *About This Site*, INST. TRANSLATIONAL HEALTH SCI., <https://www.iths.org/participate/about/about-this-site/> [<https://perma.cc/AAK7-5BNB>] (last visited June 17, 2020) (showing an example of a university webpage with resources for patients regarding research participation).

³⁰⁸ See generally, Laura L. Carlson, HIGHER ED ACCESSIBILITY LAWSUITS, COMPLAINTS, AND SETTLEMENTS, <https://www.d.umn.edu/~lcarlson/atteam/lawsuits.html> [<https://perma.cc/AAK7-5BNB>] (last visited June 17, 2020) (presenting an ongoing source of website accessibility actions in higher education).

³⁰⁹ See Terese L. Arenth, *ADA Web Site Accessibility Claims on the Rise: Practical Strategies for Defense*, 23 J. INTERNET L. 1, 13 (2019) (“The body of case law that has developed around ADA Web site compliance has been almost universally pro-plaintiff.”); *Robles v. Domino’s Pizza, LLC*, 913 F.3d 898, 905–07 (2019), *cert. denied*, 140 S. Ct. 122 (2019) (reversing district court’s grant of a web site operator’s motion to dismiss on grounds that the ADA applied to the website and that the operator received fair notice of that fact).

³¹⁰ Rios et al., *supra* note 37, at 2137.

³¹¹ 28 C.F.R. § 36.302(a) (2019) (“A public accommodation shall make reasonable modifications in policies, practices, or procedures, when the modifications are necessary to afford goods, services, facilities, privileges, advantages, or accommodations to individuals with disabilities, unless the public accommodation can demonstrate that making the modifications would fundamentally alter the nature of the goods, services, facilities, privileges, advantages, or accommodations.”).

from specific populations would show whether or not there were significant differences that could be attributed to the accommodations.³¹²

Some researchers justify exclusion of people with an intellectual disability by claiming that the accommodations needed to provide informed consent would, themselves, fundamentally alter the nature of the study.³¹³

Given the mandate that all medical equipment must be accessible, it is difficult to imagine a court crediting a healthcare provider's argument for exclusion based on the need to obtain or alter existing equipment for the research study.³¹⁴ However, a study that takes place at a clinical trial that does not provide healthcare may gain traction with this argument.³¹⁵

In *PGA Tour v. Martin*, the Supreme Court made clear that a change in equipment does not justify discrimination. Rather, the difference must be one that would be a "fundamental alteration" of the character of the activity.³¹⁶

³¹² See Rita Hamilton, Simon Driver, Shayan Noorani, Librada Callender, Monica Bennett & Kimberley Monden, *Utilization and Access To Healthcare Services Among Community-Dwelling People Living With Spinal Cord Injury*, 40 J. SPINAL CORD MED. 321, 327 (2017) (stating that when building new and retro-fitting existing medical facilities it is critical to consider the principle of "universal design", which ensures that accessibility to buildings and public spaces is fully accessible for people with disabilities."); see also *Universal Design*, CTR. FOR AN ACCESSIBLE SOC'Y, <http://www.accessiblesociety.org/topics/universaldesign/> [<https://perma.cc/34GN-KM5C>] (last visited June 17, 2020) ("Universal design is an approach to design that works to ensure products and buildings can be used by virtually everyone, regardless of their level of ability or disability.").

³¹³ See Teresa Iacono & Vanessa Murray, *Issues of Informed Consent in Conducting Medical Research Involving People with Intellectual Disability*, 16 J. APPLIED RES. INTELL. DISABILITIES 41, 49 (2003) (reviewing the challenges of obtaining informed consent in a study including people with intellectual disabilities but concluding that modifications could be made to provide sufficient protection; "[i]n universities, with developed research cultures, there is an implicit understanding of a need to protect potentially vulnerable participant groups, while ensuring that demands placed on researchers are not so restrictive as to preclude valuable research.").

³¹⁴ Rios et al., *supra* note 37, at 2141 ("Ideally, if universal design, accommodations, or both are provided with disabilities should be able to participate in some or all research-related activities.").

³¹⁵ A study being advertised by Duke University's Preston Robert Tisch Brain Tumor Center, a private entity, lists exclusions which provide good illustrations of an accommodation argument. One such exclusion involves the ability of patients to use the imaging equipment used in the study. It excludes "[p]atients who cannot undergo MRI or SPECT due to obesity or to having certain metal in their bodies (specifically pacemakers, infusion pumps, metal aneurysm clips, metal prostheses, joints, rods, or plates)." *History of Changes for Study; NCT01009866*, CLINICALTRIALS.GOV (March 18, 2015), https://clinicaltrials.gov/ct2/history/NCT01009866?V_1=View [<https://perma.cc/6RK6-JD5W>].

³¹⁶ *PGA Tour, Inc. v. Martin*, 532 U.S. 661, 683 (2001) ("[T]he use of carts is not itself inconsistent with the fundamental character of the game of golf. From early on, the essence of the game has been shotmaking—using clubs to cause a ball to progress from the teeing ground to a hole some distance away with as few strokes as possible.").

However, should that exclusion disparately affect people with disabilities, then the sponsor would have to provide a safety justification that withstands the factual scrutiny of the court.³¹⁷ This could violate requirements of the ADA mandating accessible medical equipment.³¹⁸ Moreover, if the lack of accessibility was a feature of the facility or the medical equipment, the feature would have to be modified. The exclusion of “obesity” raises other issues. While obesity itself may not be a disabling condition, if the obesity is due to a qualified condition exclusion of an obese participant too may be illegal. In general, it seems likely that this study would exclude an individual who could not access MRI equipment without modification, regardless of reason, which is illegal.

Another reason why study designs that exclude people living with disabilities may violate the ADA comes from the Supreme Court’s decision in *Lane*.³¹⁹ There, the Court found that the ADA prohibited preemptive, categorical exclusions. Instead, it required that covered entities make decisions on accommodations based on the facts of individual situations.³²⁰

Some of the exclusions of people living with disabilities in study protocols are shockingly direct. For example, a study posted on the NIH’s Clinical Trials website explicitly states that a “[m]ajor medical illnesses or psychiatric impairments that, in the investigator’s opinion, will prevent administration or completion of protocol therapy.”³²¹ This kind of exclusion is similar to the preemptive restrictions criticized in *Lane*. Without specific proof that an individual had demonstrated behavior inconsistent with inclusion, such sweeping prohibitions are unlikely to be found appropriate.³²²

³¹⁷ See *Tennessee v. Lane*, 541 U.S. 509, 533 (2004) (“[O]rdinary considerations of cost and convenience alone cannot justify a State’s failure to provide individuals with a meaningful right of access to the courts.”).

³¹⁸ Pendo, *supra* note 209, at 33.

³¹⁹ *Lane*, 541 U.S. at 509.

³²⁰ *Id.* at 531–32.

³²¹ Gary Archer, *DC Migration Study for Newly-Diagnosed GBM (ELEVATE)*, CLINICALTRIALS.GOV (Nov. 7, 2017), https://clinicaltrials.gov/ct2/show/study/NCT02366728?term=NCT02366728&rank=1&show_desc=Y#desc [<https://perma.cc/W2DN-FP6T>].

³²² This assumes that the excluded plaintiff does indeed have a “qualified disability” rather than just a pattern of noncompliant behavior. See generally Carolyn Mason, *The Social Maladjustment Exclusion: Leaving a Category of Students Behind and the Problem with State and Judicial Interpretation of Congressional Intent*, 19 U.D.C. L. REV. 91 (2016) (reviewing cases where courts distinguish between mental disability and social maladjustment).

G. Exclusion from Research Conducted by Entities Which Provide Health Care to the Public

Research studies conducted by entities which provide healthcare to the public are subject to both Title II and Title III of the ADA.³²³ Section 1557 of the Affordable Care Act has added another layer of protection by prohibiting discrimination against patients on the basis of disability status.³²⁴ It also made clear that its protections extended to all entities who receive any federal funding, even if the discrimination takes place in a division that does not provide healthcare.³²⁵ This is particularly relevant to research because many academic medical centers have created separate entities to partner with private sponsors.³²⁶

³²³ For an overview of how Title II, Title III, and the Rehabilitation Act of 1973 overlap in prohibiting discrimination associated with receiving healthcare, see ACCESS TO MEDICAL CARE, *supra* note 254, at 1 (“Titles II and III of the ADA and Section 504 require that medical care providers provide individuals with disabilities: full and equal access to their health care services and facilities; and reasonable modifications to policies, practices, and procedures when necessary to make health care services fully available to individuals with disabilities, unless the modifications would fundamentally alter the nature of the services (i.e. alter the essential nature of the services).”).

³²⁴ 42 U.S.C. § 18116.

³²⁵ See *Rumble v. Fairview Health Servs.*, No. 14-CV-2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (citations omitted) (“[A]s long as part of an organization or entity receives federal funding or subsidies of some sort, the entire organization is subject to the anti-discrimination requirements of Section 1557. A potential plaintiff need not seek medical care specifically from the part of the organization that receives federal funding. Rather, the organization is only required to have a health program or activity that receives federal financial assistance.”); Allison M. Tinsey, Comment, *Regulating Relief: Private Right of Action Jurisprudence in Healthcare Discrimination Cases*, 20 RICH. PUB. INT. L. REV. 305 (2017) (reviewing extension of private rights of action provided by Section 1557).

³²⁶ See NAT’L COUNC. ON DISABILITY, MONITORING AND ENFORCING THE AFFORDABLE CARE ACT (ACA) FOR PEOPLE WITH DISABILITIES (2016) (“If one part of an entity that is principally engaged in providing or administering health services or health insurance coverage receives federal funding, the entire entity is forbidden to discriminate.”); see also *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1049 (5th Cir. 1984) (finding that a private hospital receiving Medicare and Medicaid payments is subject to Section 504); *Rumble*, 2015 WL 1197415, at *12 (citation omitted) (quoting 42 U.S.C. § 18116) (“According to the ACA, entities that are subject to the anti-discrimination provisions in Section 1557 include ‘any health program or activity, *any part* of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance,’ or ‘any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).’ Thus, as long as part of an organization or entity receives federal funding or subsidies of some sort, the entire organization is subject to the anti-discrimination requirements of Section 1557.”).

H. Is Exclusion from a Clinical Trial Exclusion from Healthcare?

The focus of current clinical drug trials to find an effective treatment for the novel coronavirus are taking place in hospitals with participants who are extremely sick.³²⁷ It is well established that entities providing healthcare to the public cannot discriminate based on disability.³²⁸ So if the only healthcare available involves participating in a clinical trial—is exclusion from a clinical trial exclusion from healthcare? While this point is not essential to making a prima facie claim of disability discrimination, since a clinical trial is an activity of a covered entity, it would strengthen the plaintiff's position. There are strong arguments in favor of making such a claim. The increasing importance of clinical trials as a component of the U.S. healthcare system and the persistent advertising by sponsors of clinical trials have created a public climate³²⁹ in which access to clinical trials is perceived as a standard part of receiving medical care.³³⁰

Writing about the vulnerability of patients seeking access to Drug Trials, bioethicist Jerry Menikoff noted that in a situation where “the existing treatments for the patient's illness are unsatisfactory, and participation in the study offers some possibly more satisfactory treatment . . . that study—with its offer of access to some new treatment by participating in the study—might well be the best therapeutic option.”³³¹ This is especially true when the only effective treatment involves enrollment in a clinical trial. Without other

³²⁷ See, e.g., *Efficacy of Convalescent Plasma Therapy in Severely Sick Covid-19 Patients*, CLINICALTRIALS.GOV, <https://clinicaltrials.gov/ct2/show/NCT04346446> [<https://perma.cc/GBR9-B8LV>] (last updated June 12, 2020) (detailing one clinical drug trial for COVID-19 treatments and the health of the participants); Roni Caryn Rabin, *Steroids Can Be Lifesaving for Covid-19 Patients*, *Scientists Report*, N.Y. TIMES (Nov. 2, 2020), <https://www.nytimes.com/2020/09/02/health/coronavirus-steroids.html> [<https://perma.cc/N9SY-9NXJ>] (describing the results of studies treating severely ill patients with steroids).

³²⁸ *Health Care and the Americans with Disabilities Act*, ADA NAT'L NETWORK, <https://adata.org/factsheet/health-care-and-ada> [<https://perma.cc/RDP2-SEB5>] (instructing “[h]ealth care organizations that provide service to the public” to fulfil their legal obligation by “provid[ing] full and equal access for people with disabilities Reasonable modifications of policies, practices, and procedures Effective Communication [and] Accessible Facilities”).

³²⁹ An example of this comes from the publicity surrounding former President Jimmy Carter's announcement on December 6, 2015, to his Sunday School class that he was now free of the brain cancer with which he had been diagnosed six months before. Andrew Weil, *What Cured Jimmy Carter's Cancer?*, DR. WEIL BLOG (Dec. 11, 2015), <https://www.drweil.com/health-wellness/body-mind-spirit/cancer/what-cured-jimmy-carters-cancer> [<https://perma.cc/6JDT-S429>].

³³⁰ *What Are Clinical Trials and Studies?*, NAT'L INST. ON AGING, <https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies> [<https://perma.cc/8S79-CBRK>] (last reviewed Apr. 9, 2020).

³³¹ Jerry Menikoff, *The Vulnerability of the Very Sick*, 37 J.L. MED. & ETHICS 51, 55 (2009).

options for getting well, it is hard to argue that participants made a choice between treatment and research.

Until recently, it was generally understood that decisions related to medical care were not covered by the ADA. This was based on a series of cases involving third party attempts to interfere with parents' decisions to withhold life-sustaining care from critically ill infants.³³² However, as Sam Bagenstos explains in a recent piece in the Yale Law Journal Forum, these cases may not apply to the current situation. He writes that "[t]he refusal to provide coronavirus treatment to patients with pre-existing disabilities" who, either directly or through surrogate decision makers, assert that they want to be treated, is the exact opposite of preventing family members from making decisions about when to withdraw treatment.³³³ Citing the Supreme Court in *Pennsylvania Department of Corrections v. Yeskey*,³³⁴ he argues that whether or not Congress anticipated the ADA being applied to rationing of care in pandemics, "the fact that a statute can be 'applied in situations not expressly anticipated by Congress does not demonstrate ambiguity.'"³³⁵

I. Is This a Claim that People Living with Disabilities Have a Right to Participate in Research Studies?

Prohibiting disability-based discrimination is not the same as claiming a right to participate in any particular clinical trial just as prohibiting sex discrimination is not the same as claiming a right to any particular job. Readers of this article are likely to ask whether seeking access to a clinical trial is a variation of the arguments already rejected in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*³³⁶ that there is a

³³² See LAURA ROTHSTEIN, DISABILITIES AND THE LAW § 10:2 (4th ed.), Westlaw (database updated October 2020) (explaining the history of the case law relating to medical treatment of infants with disabilities); *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1289, 1294 (11th Cir. 2005) (observing that the Rehabilitation Act, like the ADA, was never intended to apply to decisions involving medical treatment); *Fitzgerald v. Corr. Corp. of Am.*, 403 F.3d 1134, 1144 (10th Cir. 2005) (finding that inmate's claims under the Rehabilitation Act and ADA were properly dismissed for failure to state a claim because they were based on medical treatment decisions).

³³³ Bagenstos, *supra* note 20, at 24.

³³⁴ 524 U.S. 206 (1988).

³³⁵ Bagenstos, *supra* note 20, at 23 (quoting *Yeskey*, 524 U.S. at 212).

³³⁶ See *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 723 (D.C. Cir. 2007), *cert. denied*, 128 S. Ct. 1069 (2008) (drawing an analogy to the doctor/patient relationship and noting that there was no obligation under the common law of the United States for any individual physician to provide treatment to any individual patient); Jerry Menikoff, *Beyond Abigail Alliance: The Reality Behind the Right to Get Experimental Drugs*, 56 KAN. L. REV. 1045, 1056 (2008) (noting that even if the Court had found a constitutional right, "[t]he FDA would not have been ordered to take any active measures to make sure the plaintiffs could indeed obtain these drugs. Nor would a victory have provided

Constitutional right to access possibly life-saving drugs before they are approved for sale by the FDA. It is not. Rather the claim here is the right to be free of discrimination based on disability. The distinction is most clear when considering Title III of the ADA which applies to private entities offering public accommodations. All of these private entities are free to refuse service on any ground other than illegal discrimination. The same applies to a public entity, like a university or one of the service academies, which are free to establish any admission criteria they want, so long as they are not based on illegal discrimination. Nor is the issue of lack of access solved by the federal and state “right to try” statutes passed in response to the Supreme Court’s denial of *certiorari* in *Abigail Alliance*. These statutes merely streamlined existing “compassionate use” policies³³⁷ that removed legal impediments preventing the FDA from granting individual waivers for access to unapproved drugs.³³⁸ They did not impose any obligations on the entities, public or private, who were conducting the drug trial. So, while there is no constitutional right or statutory entitlement to participate in a clinical trial, there can be no exclusion based on illegal discrimination.

CONCLUSIONS

This article is the first to move the exclusion of people living with disabilities from research studies from the category of moral or ethical wrong to that of actionable legal wrong. It does so in two stages. First, this article marshals the available evidence for exclusion of people living with disabilities from research studies, details the harm of exclusion, and addresses the excuses for exclusion. Second, having defined the problem, it then identifies legal remedies, primarily under the Americans with Disabilities Act, that are available to individuals who experience disability-based discrimination across the spectrum of research studies, whether funded or regulated by the federal government or conducted by a private entity. The work here is similar to that which has been done to address the exclusion of other populations historically both mistreated by and excluded from research studies, including women, African Americans, prisoners, and the elderly.

the plaintiffs with any right to order drug companies, or any other private individuals or organizations, to provide the drugs.”).

³³⁷ See *Expanded Access*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/public-health-focus/expanded-access> [<https://perma.cc/6QFX-VRPS>] (last updated Apr. 27, 2020) (providing an overview of compassionate use).

³³⁸ In addition to the regular “right to try” statutes, Congress has given the FDA considerable power to expand access to otherwise restricted drugs and biologics during an emergency. See, e.g., Joyner, *supra* note 17 (“This expanded access program will provide access to investigational convalescent plasma for patients in acute care facilities infected with SARS-CoV-2 who have severe or life-threatening COVID-19, or who are judged by a healthcare provider to be at high risk of progression to severe or life-threatening disease.”).

However, it is only recently that the U.S. government has recognized people living with disabilities as a population experiencing disparately worse health outcomes and linked these outcomes to exclusion from research. In so doing, it is several years behind governments in Europe and the U.K. which have already passed laws legislating inclusion.

The need to right a historic wrong, the exclusion of people living with disabilities from research studies, is particularly acute as the United States is facing COVID-19—a challenge demanding extraordinary resources of every kind and testing our commitment to care equally for all our citizens. As drug therapy for COVID-19 is experimental and many drugs are only available by enrolling in research studies, there is considerable urgency to make sure that whatever their care setting—public or private, nursing home or out-patient—people living with disabilities have equal access to care. In concluding that the ADA mandates inclusion in research studies, I am well aware that despite widespread public, bipartisan support, the ADA's history from passage to today has been one of vigorous litigation seeking to limit its scope. To argue that people living with disabilities who are excluded from a research study could invoke the ADA's protection is not to underestimate the complexity of this task or to be overly optimistic about the likelihood of successfully achieving accessibility to every kind of research study. Instead, this article intends to frame exclusion from research studies as the kind of discrimination that is protected by existing anti-discrimination laws and to identify a framework for matching the type of research and the kind of disabling condition to the relevant provisions of the ADA. Now is the time to stop looking at inclusion of any underrepresented population as an issue of ethics or even social justice but rather as a legal entitlement flowing from anti-discrimination laws which, so far, have never been used to demand access to research studies.